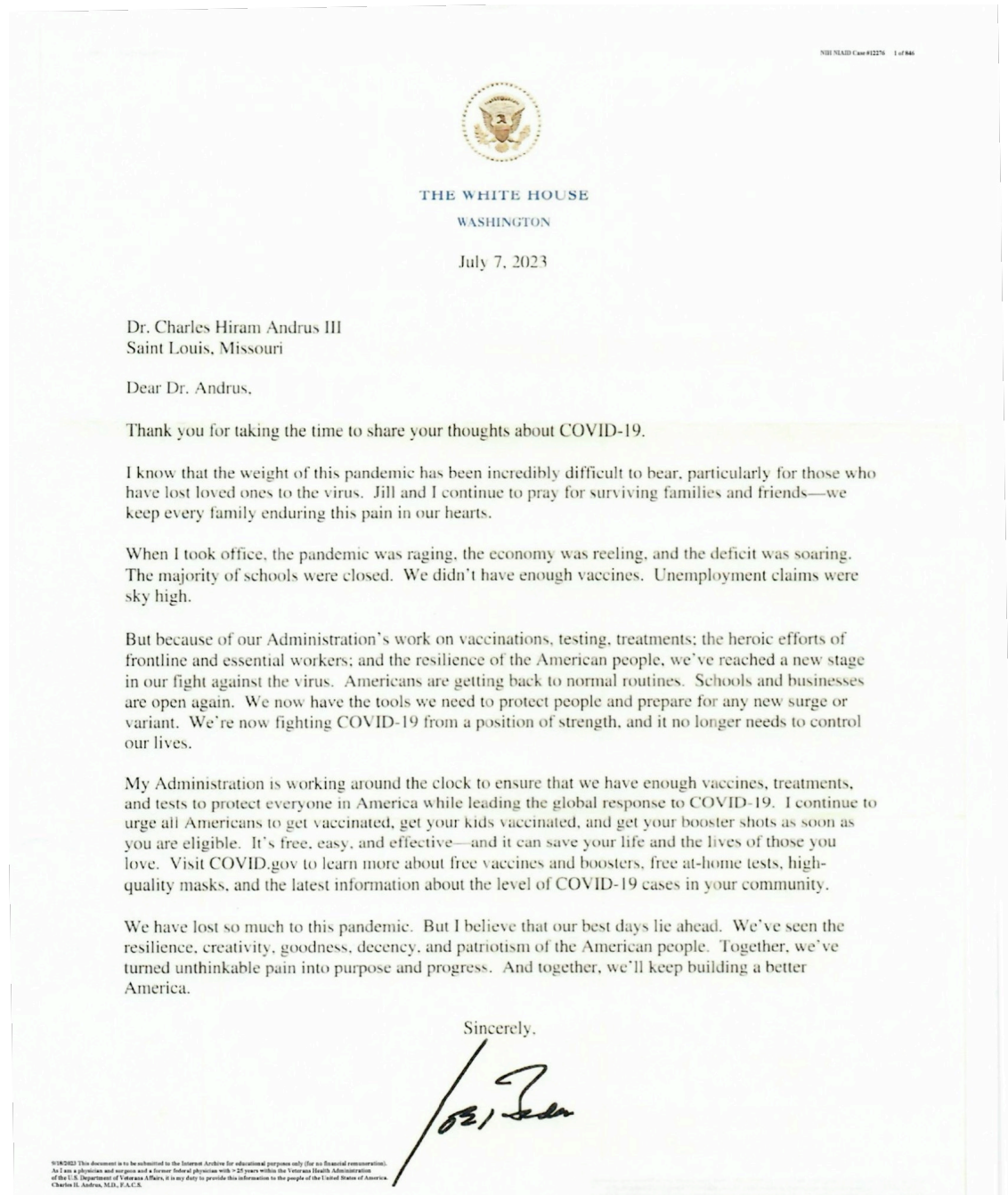


**Book 4: Response from President Biden regarding the summary of Book 1: *Dear Mr. President: COVID-19 and Where We Went Wrong***

<https://archive.org/details/book-1-dr-mr-president.-covid-19-and-where-we-went-wrong-2023-02-02/mode/1up>

NIH NIAID Case #12276









THE WHITE HOUSE

WASHINGTON

July 7, 2023

Dr. Charles Hiram Andrus III  
Saint Louis, Missouri

Dear Dr. Andrus,

Thank you for taking the time to share your thoughts about COVID-19.

I know that the weight of this pandemic has been incredibly difficult to bear, particularly for those who have lost loved ones to the virus. Jill and I continue to pray for surviving families and friends—we keep every family enduring this pain in our hearts.

When I took office, the pandemic was raging, the economy was reeling, and the deficit was soaring. The majority of schools were closed. We didn't have enough vaccines. Unemployment claims were sky high.

But because of our Administration's work on vaccinations, testing, treatments; the heroic efforts of frontline and essential workers; and the resilience of the American people, we've reached a new stage in our fight against the virus. Americans are getting back to normal routines. Schools and businesses are open again. We now have the tools we need to protect people and prepare for any new surge or variant. We're now fighting COVID-19 from a position of strength, and it no longer needs to control our lives.

My Administration is working around the clock to ensure that we have enough vaccines, treatments, and tests to protect everyone in America while leading the global response to COVID-19. I continue to urge all Americans to get vaccinated, get your kids vaccinated, and get your booster shots as soon as you are eligible. It's free, easy, and effective—and it can save your life and the lives of those you love. Visit [COVID.gov](https://www.covid.gov) to learn more about free vaccines and boosters, free at-home tests, high-quality masks, and the latest information about the level of COVID-19 cases in your community.

We have lost so much to this pandemic. But I believe that our best days lie ahead. We've seen the resilience, creativity, goodness, decency, and patriotism of the American people. Together, we've turned unthinkable pain into purpose and progress. And together, we'll keep building a better America.

Sincerely,

A handwritten signature in black ink, appearing to read "Joe Biden", with a long, sweeping diagonal line extending from the bottom left of the signature.



150 Emerald Green Ct  
Creve Coeur (St. Louis), MO 63141  
Home: 314-455-9482  
Pam's phone: 314-809-9634

April 27, 2023

The Honorable Joseph Biden  
President of the United States of America  
c/o The Honorable Denis McDonough  
Secretary, U.S. Department of Veterans Affairs  
[Denis.McDonough@va.gov](mailto:Denis.McDonough@va.gov)  
1600 Pennsylvania Avenue, NW  
Washington, DC. 20500  
202-456-1414

Dear Mr. President:

Please excuse my straightforwardness but having been involved in the Veterans Health Administration of the U.S. Department of Veterans Affairs from April 8, 1982 to November 3, 2022, and as a federal pensioner now under the auspices of the U.S. Office of Personnel Management (OPM), you're still are my boss—so this is my exist interview with my boss: (1) from my VA clinical position as a former Physician and Surgeon, Veterans Health Administration, U.S. Department of Veterans Affairs and (2) an explanation of the >14 lbs of documentation I sent to you on September 24, 2022, USPS Priority mail: 9410 8036 9930 0153 7265 90.

Throughout my professional life, I have tried to the best of my abilities to be a responsible, dedicated, accountable Federal Physician and Surgeon under the auspices of the Veterans Administration (today, Veterans Health Administration [VHA]) in the care of every Veteran patient that presented to me over the last 40 years. On the evening of March 3, 2004, after the oral arguments that day were concluded before the U.S. Court of Appeals for the Federal Circuit in *Andrus v. VA*, Docket # 03-3162, the Andrus family [my two oldest sons (we have five boys: Charlie, Patrick, Thomas, Michael, and Timothy), my wife, Pamela Bergkamp Andrus, and myself, Charles Hiram Andrus, III, M.D., F.A.C.S.] went to the Lincoln Memorial to read the last sentence inscribed on the north inner wall of the Lincoln Memorial:

([https://www.shapell.org/manuscript/abraham-lincoln-with-malice-toward-none-second-inaugural-aqs/?gclid=EAIaIQobChMInvrX3KOz\\_gIVjyyzAB0\\_LAIQEAAAYASAAEgK3avD\\_BwE#transcripts](https://www.shapell.org/manuscript/abraham-lincoln-with-malice-toward-none-second-inaugural-aqs/?gclid=EAIaIQobChMInvrX3KOz_gIVjyyzAB0_LAIQEAAAYASAAEgK3avD_BwE#transcripts)):



"With malice towards none; with  
charity for all; with firmness in  
the right, as God gives us to see  
the right, let us strive on to finish  
the work we are in; to bind  
up the nations wounds; to care  
for him who shall have borne  
the battle, and for his widow  
and his orphan — to do all  
which may achieve and cherish  
a just, and a lasting peace am-  
ong ourselves, and with all na-  
tions."

Abraham Lincoln.

Throughout my professional life as a VA Physician and Surgeon, I have tried to the best of my abilities in my daily practice and interaction with Veteran patients, to do that which President Lincoln admonished all of us to do:

**...to care for him who shall have borne the battle, and for his widow and his orphan... .**

While this interaction with you today is my affirmation and assessment of the forty years of my personal dutiful commitment to the United States of America (USA), it was and is my continued response to our collectively-mandated commitment to the rights of all individual Veteran patients to good and appropriate healthcare through the words of President Lincoln directed by the United States of America. Truthfully, this commitment should not only be for Veteran patients but all individuals of the USA. Over the last 40 years, I have witnessed bureaucratic intolerance, obfuscation, misdirection, and misinterpretation of the intent of federal laws; political arrogance and greed, and, most of all, self-serving stupidity towards our fellow man that unnecessarily led to increased morbidity and mortality of Veteran patients and all Americans in general. For my continued fulfillment to my duty to our country as a Federal Physician and Surgeon, on September 24, 2022, I sent to you >14 lbs of rough-draft documentation by U.S.P.S. priority mail (USPS Priority mail: 9410 8036 9930 0153 7265 90) in three books (draft collections in approximately chronological order) entitled:

Book 1: *Dear Mr. President: COVID-19 and Where We Went Wrong*

Book 2: A cover letter to Secretary McDonough with supporting material regarding the bureaucratic obfuscation and stupidity that resulted in my erasure from the history of the Edward Hines, Jr. VAH and my becoming an “unperson” in the records of the U.S. National Archives

Book 3: *Dear Mr. President: “...to care for him who shall have borne the battle...” A. Lincoln.*

U.S. Postal Service as Priority Mail to: the US Department of Veterans affairs (offices of the Secretary of the Department of Veterans Affairs [USPS tracking number: 9410 8036 9930 0153 7266 20], the offices of the General Counsel (and DEAO) per the direction of Michael Hogan, J.D. in our phone conversation in the Spring of 2022 to copy all to the OGC [USPS tracking number: 9410 8036 9930 0153 7266 06]); The National Institute of Allergy and Infectious Diseases as per the establishment of NIAID Case file #12276 [accessible to anyone under the FOIA] by Kara Harris MPH [USPS tracking number: 9410 8036 9930 0153 7286 24] at the direction of the Director, Anthony Fauci, M.D. [USPS tracking number: 9410 8036 9930 0153 7266 13]; and the U.S. Constitutional-responsible and accountable authority for the Executive Branch of the Federal Government, President Joseph Biden [USPS tracking number: 9410 8036 9930 0153 7265 90] and others.

Mr. President, in short, we as a nation are continually misleading ourselves and our society by **Sins of Omission** (telling half-truths by withholding pertinent details), employment of obfuscating **Euphemisms** (see George Carlin’s HBO presentation over 3 decades ago: <https://www.youtube.com/watch?v=isMm2vF4uFs>), and justifying these half-truths before society and our minds by the syndrome described in the Medical literature as **Chronic Denial** (Attachment **0.84 1977 Gilman letter Yale University New Haven.pdf**).

Today, it is common place to *Lie with Statistics* ([https://online225.psych.wisc.edu/wp-content/uploads/225-Master/225-UnitPages/Unit-07/Huff\\_StatisticsBook\\_1954.pdf](https://online225.psych.wisc.edu/wp-content/uploads/225-Master/225-UnitPages/Unit-07/Huff_StatisticsBook_1954.pdf)). All Departments of the Executive Branch of the U.S. Federal Government have gotten extremely proficient at (1) electronic overwriting and (2) changing officially-named document titles and thus URLs to render the past history of a U.S. government document relatively, legally non-discoverable requiring an exact knowledge of the precise URL and then necessitating a reviewing through the Wayback Machine of the Internet Archive which is a non-governmental, not-for-profit Internet Archive tool: <https://archive.org/web/>. If one wants to really cover-it-up / loose the document as non-discoverable, one need only change the title of the document (e.g. VHA Handbook 1400.1 to VHA Handbook 1400.01) and the latest URL may no longer be

similar to the previous URL so that discovery of previous versions of a federal document through the Wayback Machine are virtually impossible! An example of the morphing process to **COVER-UP corrections of previous versions that are NOT discoverable** in the VHA Handbook RESIDENCY SUPERVISION Directive over time are examples of legal obfuscation / essentially non-discoverability by overwriting and changing URLs:

- (1) VHA 1400.1 RESIDENT SUPERVISION, October 25, 2001, URL:  
[http://web.archive.org/web/20041028182959/https://www.va.gov/oaa/1400\\_1hk\\_Oct2001.doc](http://web.archive.org/web/20041028182959/https://www.va.gov/oaa/1400_1hk_Oct2001.doc);
- (2) VHA 1400.01 RESIDENT SUPERVISION, December 19, 2012:  
[https://www.va.gov/OPTOMETRY/docs/VHA\\_Handbook\\_1400-01\\_Resident\\_Supervision\\_12-19-2012.pdf](https://www.va.gov/OPTOMETRY/docs/VHA_Handbook_1400-01_Resident_Supervision_12-19-2012.pdf) ; and
- (3) VHA 1400.01 SUPERVISION OF PHYSICIAN, DENTAL, OPTOMETRY, CHIROPRACTIC, AND PODIATRY RESIDENTS, November 7, 2019:  
[https://www.va.gov/OPTOMETRY/docs/1400\\_01\\_D\\_20191107.pdf](https://www.va.gov/OPTOMETRY/docs/1400_01_D_20191107.pdf)

During COVID-19, the FDA, the NIH, the CDC, the VHA, etc. demonstrated their understanding, proficiency, and mastery of these QUESTIONABLE, governmentally-condoned methodologic technics of obfuscation in all aspects of our lives over the last three years during the American COVID-19 epidemic. Most importantly, in the FDA'S, NIH'S, etc's overwhelming short-sighted promotion of:

- (1) only **prophylaxis (Active Immunization)** (e.g. with mRNA vaccines) with the subsequent development of **endogenous antibodies**: i.e.: non-infected individuals responding to the production of IgG to the vaccines); and
- (2) in deference to **treatment** within 72-120 hours of the contraction of the virus (becoming infected) **TO EVERY INDIVIDUAL AMERICAN** who contracted SARS-CoV-2 by the individual with **TREATMENT** with **Passive Immunization**: COVID-19 Convalescent Plasma, monoclonal antibodies, monoclonal antibody cocktails, etc. and, most importantly synergistically, with available **antivirals**. (i.e.: Remdesivir under an EUA from May 1, 2020 and subsequently as the FDA approved prescription drug, VEKLURY, NDA# 214787 since October 22, 2020  
[https://www.accessdata.fda.gov/drugsatfda\\_docs/applletter/2020/214787Orig1s000ltr.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2020/214787Orig1s000ltr.pdf), and now more recently with Paxlovid which is still under an EUA since December 22, 2021.  
<https://web.archive.org/web/20211222180424/https://www.fda.gov/media/155049/download> )

Mr. President: Why is the previous paragraph so important? As a retired federal-physician, I will receive a pension (hopefully recalculated) through the Office of Personnel Management (OPM) for the rest of my life as with every other federal employee under the Federal Employee Retirement System (FERS). For example, unlike me who bureaucratically was "lost" by the VA with the VA not yet able to appropriately calculate correctly my past gross pay for the last six years and consequently my federal pension for the rest of my life, Anthony Fauci, M.D., is scheduled to receive a purported tremendous federal pension based on the average of his top three consecutive salaries which will approximate or may surpassed your annual salary of \$400,000 which is supposed to be the "salary cap" of all federal employees.



As you are the U.S. Constitutionally-documented administrator and top executive of the Executive Branch of the U.S. Federal Government, Mr. President, **YOU ARE THE BOSS** of all federal employees--both those continuing in employment in the agencies and departments of the Executive Branch of the Federal Government and those retired pensioners, like Dr. Fauci and myself, paid under the Office of Personnel Management (OPM).

The expression: "Follow the Money" is attributed to Mark Felt's character *Deep Throat* in *All the President's Men*. Mr. President, in regards to the tragedy (>1.1 million dead and many more maimed) of the U.S. misguided *de facto* patient abandonment of COVID-19 infected individuals by withholding early treatment (<72 hours from diagnosis) (or giving it too-late during the Cytokine Cascade and the Bradykinin Storm of COVID-19 pathophysiology), **Passive Immunization** and, synergistically with **antivirals**, was the *sine qua non* of the U.S.A's collective approach in those that were infected with COVID-19. Mr. President, have your advisors coordinate for you the **addressing of the lies of omission** of all federal physicians, U.S. Medicine in general, and the medicine-federal-pharmaceutical industrial complex by following the money! (See Attachment VII SINS OF OMISSION 2022-09-05 Dear Mr. President.pdf)

If you find my assertions hard to believe, as I am still a salaried physician through OPM and therefore **you are my boss**; and, thus, it is my duty to suggest to you that you pose the question to your federal physician advisors in U.S. government employment (both active and retired) the traditional Yes/No dilemma of the rhetorical "loaded question":

**Yes or No: When are you going to stop lying to the me and the American people?**

On September 24, 2022, I sent to you >14 lbs of supportive documentation by U.S.P.S. Priority Mail (USPS Priority mail: 9410 8036 9930 0153 7265 90), so that the physician advisors of both President Trump and yourself regarding COVID-19 (e.g.: Fauci, Collins, Birks, Redfield, Hahn, Marks, , etc. could honestly discuss the complexities of the pathophysiology of COVID-19; the clinical immunotherapy difference between prophylactic vaccination of non-actively-infected individuals only (endogenous immunotherapy by **Active Immunization**) versus early treatment (<72 hours from diagnosis) with **Passive Immunization** and synergistically, **antivirals**.

As those in the FDA and NIH over the last three years took little heed (really no heed) of my message of going back to the foundational basics of clinical immunology, I doubt whether they will now. If you wish to discuss that which I have outlined in this submission (or in more detail, the >14 lbs of documentation I sent to you on September 24, 2022 by U.S.P.S. Priority Mail) and the multifaceted implications of this documentation going forward regarding our country's future please do not hesitate to call upon me. If you so desire, I will be very happy to debate before you, the foundational concepts of appropriate clinical early treatment (<120 hours from diagnosis) for the individual patient infected with the next novel virus like COVID-19 with **Passive Immunization** and synergistically with **antivirals** (when available) which has been the mainstay of the clinical TREATMENT APPROACH of infected individuals for at least a century. (i.e.: Emil von Behring in his work regarding **Passive immunization**) was awarded the first Nobel Prize in Medicine or Physiology in 1901.

<https://www.nobelprize.org/prizes/medicine/1901/behring/biographical/>

Mr. President, I'm just a General Surgeon who recalls the clinical immunologic fundamentals that he was taught regarding **Active Immunization** versus **Passive Immunization** at Saint Louis University (SLU) Medical School [the Dean euphemized the school's name to SLU School of Medicine (SLUSOM) so as not to use the school's previous initials: SLUMS]. In my mailing to you to follow via U.S.P.S. priority mail, I will enclose a copy of the 7<sup>th</sup> edition of Dr. Plotkin's textbook in my mailing to you so you might read Chapter 8.:

Plotkin SA, Orenstein WA, Offit PA, Edwards KM: *Plotkin's VACCINES*. Mr. President, please read Chapter 8: Mark K. Slifka and Ian J. Amanna: *Passive Immunization*, pages 84 – 95.  
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7151993/pdf/main.pdf>

Mr. President, please look at Figure 8.2 and the caption regarding the efficacy of passive immunity decreasing disease progression on page 88. That one figure graphically discounts everything that was done WRONG in the providing and rationing COVID-19 Convalescent Plasma, monoclonal antibodies, or monoclonal antibody cocktails late in the pathophysiology of the SARS-CoV-2 disease during the Cytokine Cascade and the Bradykinin Storm as the immunotherapies would have been (and still would be if new monoclonal antibodies were developed after each COVID-19 mutation shift) most effective during the initial viremia (with 72 hours of diagnosis) in ALL individuals infected with COVID-19.

This week, *The New-York Times* reporter David Wallace-Wells reported on his interview of Dr. Fauci entitled: "Dr. Fauci Looks Back: 'Something Clearly Went Wrong'" <https://www.nytimes.com/interactive/2023/04/24/magazine/dr-fauci-pandemic.html> . In an answer to Mr. Wallace-Wells question: "Do you think the experience of the pandemic – and the possibility of a lab origin, however remote—should change how we think about the risks and benefits of this entire field of research?" While the rest of Dr. Fauci's response speaks about the euphemism of gain-of-function research which amounts to an issue of distraction, the first sentence is a truism that all of U.S. Medicine, the U.S. Pharmaceutical Industry, and U.S. Government failed miserably to follow throughout the last three years:

You have to have a totally transparent process that involves scientific input and community input – informed community input.

Dr. Fauci did not listen (and implement in the "community") to the advice of Michael Joyner, M.D., Deborah Birx, M.D, or Arturo Casadevall, M.D. regarding early treatment (<72 hours from diagnosis) of the SARS-CoV-2 infection of the individual patient with COVID-19 Convalescent Plasma. When I wrote of our (U.S. Medicine) approach of discounting appropriate early (<72 hours from diagnosis of COVID-19 infection) of treatment with **Passive Immunization** in *Time: The Crucial Independent Variable of the COVID-19 Pandemic*, TXu002199029, Dr. Fauci responded to me through Kara Harris, MPH establishing NIAID Case #12276 with:

Thank you for your recent fax directed to Anthony S. Fauci, M.D., director of the National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health. Due to his professional responsibilities, Dr. Fauci has asked me to respond on his behalf.

**0.99 Attachment VIII NIH and FDA responses including 6-10-2020 re NIAID Case #12276.pdf**

Dr. Fauci was too busy to listen when in the prose of TXu002199029, I drew the analogy of withholding appropriate early treatment (<72 hours from diagnosis of COVID-19 infection) with COVID-19 Convalescent Plasma of COVID-19 was analogously tantamount on a national level

to the withholding of penicillin in the Tuskegee Syphilis Study (“Tuskegee study of untreated syphilis in the Negro Male”) in the mid-twentieth century. On May 16, 1997, President Clinton apologized to the eight surviving Alabama share-croppers and approximately ~600 others who had died <https://clintonwhitehouse4.archives.gov/New/Remarks/Fri/19970516-898.html> President Biden, why don’t you phone President Clinton and ask him specifically what were his emotions when he delivered this apology for to those survivors on behalf of U.S. Medicine and our nation.

For that matter, Mr. President, we continue to fail to listen to and learn from history and minimize informing “the community”: e.g.:

- (1) Emil von Behring and his descriptions of antitoxins and Louis Pasteur and the rabies vaccine;
- (2) gamma globulin (the forerunner of IVIG)--utilized by a young NIAID hepatitis researcher in the late 1940s, James William Colbert, Jr., M.D. Mr. President, could you image if Dr. Fauci had alluded to the fact that Dr. Colbert had used gamma globulin (*Passive Immunization*) in the treatment of serum hepatitis at the NIAID in his interview with Dr. Colbert’s son, Stephen, last fall?  
<https://www.youtube.com/watch?v=PEOm5QhJVIE>; and
- (3) in an interview by Dr. Morrissey of *The New England Journal of Medicine* in 2018 regarding then a recent review publication: Marston HD, Paules C, **Fauci AS**: Monoclonal antibodies for emerging infectious diseases – Borrowing from history. **N Engl J Med** 2018 Apr 19; 378 (16): 1469 – 1472.  
[https://www.nejm.org/doi/10.1056/NEJMp1802256?url\\_ver=Z39.88-2003&rft\\_id=ori:rid:crossref.org&rft\\_dat=cr\\_pub%20%200pubmed](https://www.nejm.org/doi/10.1056/NEJMp1802256?url_ver=Z39.88-2003&rft_id=ori:rid:crossref.org&rft_dat=cr_pub%20%200pubmed) , in which Dr. Fauci stated in response to Dr. Morrissey:

*Dr. Morrissey:* You write in your article that several antibody therapies have been licensed for infectious diseases. What have researchers learned from the development of those therapies and for more recent attempts to create monoclonal antibodies against—say-- Ebola or Zika?

**Dr. Fauci:** Well, for example, a classic monoclonal antibody for prophylaxis against **Respiratory Syncytial Virus** has been developed with considerable success. We began thinking very intensively about this just literally over the past few years when we in rapid succession had to confront both the Ebola outbreak followed by the Zika outbreak. ...

Yes, Mr. President, since 1998, SYNAGIS (palivizumab) BLN 1252 has been an FDA approved-prescription monoclonal antibody in the prophylaxis and early treatment of Respiratory Syncytial Virus (RSV) **only** in high-risk infants. The CDC suggests that while there are 100 – 300 deaths in children less than 5 years of age annually, there are 6,000 - 10,000 adult deaths over 65 years of age annually.  
<https://www.cdc.gov/rsv/research/index.html#:~:text=58%2C000%2D80%2C000%20hospitalizations%20among%20children%20younger%20than%205%20years%20old.&text=60%2C000%2D160%2C000%20hospitalizations%20among%20adults%2065%20years%20and%20older.&text=6%2C000%2D10%2C000%20deaths%20among%20adults%2065%20years%20and%20older.>

So why has the FDA directed rationing of the access to this FDA approved prescription monoclonal antibody for a quarter of a century instead of encouraging production and stockpiling over the last quarter of a century for ***Passive Immunization*** by early treatment (<72 hours from diagnosis) for all ages who become infected with RSV?

- (4) Mr. President, on April 10, 2023, you signed into law PL-118-3 (H.J. Res. 7) <https://www.congress.gov/bill/118th-congress/house-joint-resolution/7> which rescinds President Trump's Executive Order 9994 of March 13, 2020 which declared the COVID-19 epidemic in the United States of America a Public Health Emergency (PHE). Mr. President, how are all the COVID-19 home tests and antivirals like Paxlovid going to be available as they are "FDA authorized—Emergency Use Authorization (EUA) and not FDA approved like the antiviral VEKLURY (remdesivir)? Anything that was FDA-authorized under the umbrella of an EUA during the PHE will revert to FDA status of Investigational / Experimental. Most malpractice carriers proscribe physicians under their coverage from prescribing investigational /experimental drugs or treatments without being IRB approved investigators involved in a research protocol.

Mr. President, I am just an American Board of Surgery-certified, insignificant, unknown federal physician and general surgeon of the Midwest who the VHA has officially denied even my existence between April 8, 1982, and January 22, 2002, for the last two decades before itself and the U.S. National Archives. (Mr. President, I, like Dr. Fauci, was trained by the Jesuits and self-deprecation can be a very forceful methodology in *Reductio ad Absurdum* – that is, reduce the argument to the absurd. (Please read at least the title page of: **0.1 2023-04-27 Tale of Two Presidents**) Mr. President, in my mind, I have always tried to serve our country—to the best of my ability--at the pleasure of the President of the United States. If I can be of assistance to you, please call me: 314-455-9482—my home, 314-265-1814—my cell, or, most especially, 314-809-9634—Pam's cell which is the most reliable as we tomorrow will be leaving for San Francisco to visit my home city including those sites that were instructionally foundational to me: St. Gabriel's Parish and School, St. Ignatius College Prep, and the University of San Francisco.

Mr. President, thank you very much for considering this submission.

Respectfully,

Charles H. Andrus, M.D., F.A.C.S.

Retired VHA Physician and Surgeon, U.S. Department of Veterans Affairs (1982 – 2002 and 2016 – 2022)

Former Professor, Department of Surgery, Saint Louis University SOM (2006-2022) and

Former Professor and Vice-Chairman, Department of Surgery,

Loyola University (Chicago) SOM and Chief, Surgical Services, Edward Hines, Jr. VAH (1996-2002)

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NIH Case# 12276  
VA RSSO: 286816

**Re: Phone communication from Mr. Jeffrey Stubbs 1-801-209-5978 to Pamela Andrus' cell phone: 1-314-809-9634 on 04/14/2023 at 1214 CDT**

NIH Case# 12276  
VA RSSO: 286816

April 27, 2023

Jeff Stubbs  
Acting Associate Director, RSSO  
Worklife Benefits SSU  
Human Resources Operations Office, HROO (106A6)  
Workforce Management and Consulting (106A)  
Veterans Health Administration  
US Department of Veterans Affairs  
Cell: (801) 209-5978  
Fax: (785) 228-4813  
Email: [Jeffrey.Stubbs@va.gov](mailto:Jeffrey.Stubbs@va.gov)

Dear Mr. Stubbs:

Thank you so very much for calling me on Friday, 4/14/2023, and listening to my litany of what has occurred in my involvement in the Veterans Health Administration (VHA) as a VA / University-affiliated Physician and Surgeon from 4/8/1982 – 01/22/2002 and 08/08/2016 – 11/03/2022. After our phone conversation concluded, my wife turned to me and flatly stated that it was amazing that someone who could affect a change within the VA (that is you with regards to my pension calculations) had finally listened to me after the last quarter of a century of complete dismissal by those in the hierarchy of the VA to the Andrus' family's ongoing chronic disappointment! On that evening, my son Timothy and my wife Pam drove to Kansas City to see Tim's cousin / Pam's and my niece in her final Varsity Volleyball game(s) for Gonzaga University as a senior. When Pam called me later that evening, she was in tears for your willingness to listen--as the enormity of your phone call had finally set in.



I will include attached to this e-mail the following:

1. a copy of my curriculum vitae (Attachment I)
2. The SF-50 of January 2002 in which in the section 45. Remarks, I stated that my resignation at that time was a **Constructive Discharge** and provided the corroborating scenario of what had occurred 25 years ago.(Attachment II)
3. My calculations in an Excel spreadsheet base on my reconstruction of my base pay using 38 U.S. Code §7431. (the latest VA template is of January 1, 2023) Please be advised that when I returned to the VA in August 2016, the St. Louis VAMC HR in order to offer a comparable salary consistent to what Saint Louis University (SLU) was paying me, called the business manager of the Department of Surgery of Saint Louis University School of Medicine (SLUSOM) to find out what my university salary was as a full (tenured) Professor of Surgery—which at the time was \$265,000. Please note from the AAMC book on salaries of academic physicians at that time, my salary was (and always had been) <10<sup>th</sup> percentile for a General Surgeon in the Midwest when I functioned as a General Surgeon only. (Please, when all the Pediatric Surgeons left Cardinal Glennon Children’s Hospital (CGCH) for greener pastures ~15 years ago and consistent with my American Board of Surgery certification and past training in pediatrics and pediatric surgery, I was the only General Surgeon at CGCH for 8. Only when new pediatric surgeons were hired was my salary increased for a time only to be decreased back to baseline when I returned to the University Hospital full-time.) The St. Louis VA HR took the \$265,000 and subtracted the posted base salary for a Grade 15 Step 7 physician to calculate my locality pay as a difference. – and the VA offered me a total adjusted gross pay of \$265,000 my total starting salary in July 2016. (I had been a Grade 15 Step 10 for 9 years prior to my separation as Chief of Surgery, Edward Hines, Jr. VAH in January 2002 but I was *de facto* demoted to a 15,7 as I was “a new hire” because 18 years of my VA life had been officially lost as my Official Personnel File (OPF) from 1982 to 2002 did not exist.) *Res ipsa loquitur*, *Andrus v VA*, U.S. Court of Appeals for the Federal Circuit, Docket #03-3162, was filed as and tried as an EEOC complaint (EEOC #210-A3-6145X); and, thus, I suffered a *de facto* demotion from a Grade 15, Step 10 to a Grade 15, Step 7 which is retaliation under EEOC regulations by the United States of America. (Attachment III)

As you discussed in our conversation on 4/14/2023, you can correct my pension calculations once there is a correction of my rank of my Grade 15, Step 12 to 13 over the last 3 years per the annual table postings (38 USC §7431) but that will require a higher level of authority in VACO—probably the Secretary of the U.S. Department of Veterans Affairs, Mr. McDonough.

As we spoke on Friday, 4/14/2023, and you reference three books that you had in your possession, I initially assumed that the three books were what I sent the VA, the NIH, the FDA, the CDC, and President Biden, Secretary McDonough, and VA General Counsel (the Designated Agency Ethics Officer) on September 24, 2022:

Book 1: *Dear Mr. President: COVID-19 and Where We Went Wrong*

Book 2: A cover letter to Secretary McDonough with supporting material regarding the bureaucratic obfuscation and stupidity that resulted in my erasure from the history of the Edward Hines, Jr. VAH and my becoming an “unperson” in the records of the U.S. National Archives



Book 3: *Dear Mr. President: "...to care for him who shall have borne the battle..."* A. Lincoln.

You stated you had three books that were sent to the VA. A third set of Books 2 and 3 only and my subsequent correspondence book (addendum book 2A) must have been copied from my January 30, 2023 submission by the Topeka, KS RSSO. Accompanying the return of my January 30, 2023 submission to the RSSO was cover documentation with an **undated cover letter** Attachment IV from Ms Fairfield of the Topeka, KS RSSO that arrived on my home's doorstep on February 13, 2023, in a box by U.S.P.S. priority mail with certification: marked with a certified mail sticker of: 7020 2450 0001 8086 3912 and metered postal stamp of \$32.80 postmarked Feb 08 2023. Within the box was the **undated letter on VA letterhead with pertinent--vis-à-vis incorrect--documentation from the VA RSSO.** The box on my doorstep on February 13, 2023, contains the documents that I had sent on January 30, 2023 but NOW unbound with the plastic binders that had previously bound the documents on top. (Attachments IV and V) In the undated letter on VA letterhead in the fourth paragraph was:

You should receive a lump-sum payment from the VA for any unusual annual leave on your last paycheck. TSP will be notified of your approximately 30-45 days after your retirement date. **In addition, after speaking with leadership, it was determined to return the documents you have mailed in as they are not pertinent to your salary discrepancy or the retirement.**

The obvious question, Mr. Stubbs, is: ***"Who is leadership" in the VA*** that made this decision to again forget officially my 18 years of VA service existence prior to January 22, 2002, (as my paper OPF from 4/8/1982 to 1/22/2002 has gone missing) in the calculation of my back pay deficit and my pension calculations? [(To confirm the previous statement, might I suggest that Secretary McDonough ask his secretary to go down to VACO HR and ask for all the documentation regarding the VHA Commission for the vetting of candidates for the position of VHA Under Secretary for Health (USH) of December 10, 1999. Unless that documentation has been lost or "sanitized", the candidates interviewed on that day were: Andrus, Bowen, Garthwaite, Petzel, and Roswell. If that documentation has been lost, I have a CD containing all the e-mails from my VA computer (in Wordperfect or Microsoft Word) provided by the defendant, the United States of America, to me (the plaintiff) during the discovery phase of EEOC #210-A3-6145X in Andrus v VA (U.S. Court of Appeals for the Federal Circuit) of Andrus v VA, docket case #03-3162) provided by the U.S. DOJ legal defense team on behalf of the defendant, the United States of America, during the discovery phase in 2003 with oral arguments on March 3, 2004. For that matter, if Secretary McDonough should wish confirmation of Andrus v VA Case #03-3162, he could ask his secretary to go across the street to the Madison Building to the clerk's office of the U.S. Court of Appeals for the Federal Circuit (I think room 402) and request a cassette transcript of the oral arguments on March 3, 2004, in Andrus v VA, Case #03-3162.]

**Mr. Stubbs paralleling my calculations in Attachment III, the VA should adjudicate my gross VA salary for the last > 6 years taking into account 38 U.S.C. § 7431.** (As we discussed on the phone on Friday, the adjudication will probably come from higher authority than yourself.—I would venture that higher the authority would be some individual designated by the Secretary of the U.S. Department of Veterans Affairs as the Secretary is "the VA boss" representing the Constitutional authority for the Executive Branch of the Federal Government, President Biden, who is also our boss.) **By my calculations, the VA owes me in back pay at least \$82,000 regarding my *de facto* demotion from Grade 15-10 in 2016 back to Grade 15-07. What is more, as you and I discussed on that Friday, after such an adjudication of my salary for the last six years, you will then be able to recalculate my pension *apropos* to**

**the recalculation of an adjusted annual salary average of my last three consecutive years of highest pay.**

Finally, Mr. Stubbs, the rest of this e-mail will be utilized by me to speak directly to and through the Secretary of the U.S. Department of Veterans Affairs, Mr. Denis McDonough, who I respectfully request will provide this e-mail to President Biden which includes my to President Biden sequentially following in this e-mail.

Mr. Stubbs, once again, my family and I personal thank you and will be forever in your debt for the your phone call of Friday, April 14, 2023.

Thank you for listening,

Charles H. Andrus, M.D., F.A.C.S.

**ATTACHMENTS:**

**Attachment I:** my *Curriculum vitae*: **0.3 Attachment I Andrus SLU cv8\_11\_2021.pdf**

**Attachment II: 0.4 Attachment II SF-50s including 01-19-2002 45.remarks Constructive Discharge.pdf** This file contains scans of some of my SF-50s especially that of my separation SF-50 of January 2002 in which in 45. Remarks, I have summarized the reason for the allegation of a *Constructive Discharge*

**Attachment III: 0.5 Attachment III 2023-04-18 Andrus recalc of pay and pension e-mail pt1.xlsx** An Excel Data base with my rough recalculation of a past pay deficit owed to me by the VA and the subsequent recalculation of my pension.

**Attachment IV: 0.6 Attachment IV 2023-02-13 VA RSSO 120 SE 6<sup>th</sup> suite 102 Topeka\_KS .pdf.zip** The undated cover letter returned to me in the box from the RSSO postmarked February 8, 2023, and arrived at my doorstep February 13, 2023.

**Attachment V: 0.7 Attachment V 2023-01-29 cover Andrus e-mail transmission to VA.pdf** A copy of my e-mail cover letter and documentation of January 30, 2023 to Ms Fairfield of the Topeka, KS RSSO.

**Attachment VI: 0.8 Attachments VI Email correspondence regarding Dr Hawley involvement in VA-University affiliation.pdf** Dr. Andrus correspondence after his being a member of the Committee of Regional Interviewers of candidates for Fellowship in the American College of Surgeons on April 16, 2023.

**0.81 Chapter 3 The Dog Lab.pdf**

**0.82 14 Chapter 14 Discussions and Reflections.pdf**

**0.83 2006\_06\_18-Whatever\_you\_say\_Doc.pdf**

**0.84 1977 Gilman letter Yale University New Haven.pdf**

**Attachment VII: 0.9 Attachment VII SINS OF OMISSION 2022-09-05 Dear Mr. President**

**0.99 Attachment VIII NIH and FDA responses including 6-10-2020 re  
NIAID Case 12276.pdf**

P.S.: Dear Secretary McDonough:

Over the course of the last twenty-five years, I have tried to be a responsible federal physician raising my concerns regarding *de facto* disregard for patient rights by some physicians and surgeons of the Veterans Health Administration as promised in the University/VA affiliation, VA Policy Memorandum #2. I have tried in every way, shape, and form to bring this to the attention of the multiple administrations of the Veterans Health Administration (VHA). I failed to obtain even an acknowledgment of my VA existence from 1982 to 2002 by VACO as “my opf” was somehow misplaced; and, thus, my very existence from 1982 to 2002 historically was not locatable at the Edward Hines, Jr. VAH of which I was the Chief of Surgery for over five years and in the U.S. National Archives when searched several years ago by the personnel of the St. Louis VAMC Human Resources Department. My “non-discoverability” thus led to the continuation of the incorrect designation of my Grade 15, Step 7 and subsequently delayed 8 to 10 (I am, at present, by Title 38, U.S.C. Sec 7431 a Grade 15, Step 13

<https://www.va.gov/OHRM/Pay/2022/PhysicianDentist/PhysDentPodBaseLongevityRates.pdf>. My *de facto* Orwellian “1984 unperson” status as resulted from denial of my physician existence from 1982 to 2002 within the Veterans Health Administration (VHA) of U.S. Department of Veterans Affairs (DVA) had the far-reaching ramifications of my underpayment for the last six years, my wrongly calculated pension for my annuity for the future, and, for history sake, the loss to history of my very existence as the Chief of Surgery, Edward Hines, Jr. VAH, from 1996 to 2002. As a VA physician and surgeon, I am honored to have been the Chief of Surgery of the Edward Hines, Jr. VAH from 1996 to 2002 as the Hines VAH was the clinical origin-site of the implementation of University / VA affiliation in 1946 under PL-79-293 championed by Drs. Hawley and Magnuson, General Omar Bradley, and President Harry S. Truman.

By being “in the clinical trenches” as a physician and surgeon over the last 40 years, the VA taught me how to create a paper trail. So, I have documented for history in multiple ways my story and that of my experience (even though the VA denied my existence from 1982 to 2002) in the VA as I will list below.

Mr. Secretary, I truly believe in the mission of the VA and its charge from President Abraham Lincoln 158 years ago:

...to care for him who shall have borne the battle, and his widow and his orphan...

Much of the details are in Book 3 by my submission as the claimant before the U.S. Copyright Office of the Library of Congress:

*Dear Mr. President: ...to Care for Him who Shall have Borne the Battle... A. Lincoln*

Hopefully, I have cataloged for history, in some small way by my submissions as the claimant, the nine documents in regards to the VA that make up Book 3. Also, three documents I submitted as the claimant to the U.S. Copyright Office of the Library of Congress that are part of Book 1:

*Dear Mr. President: COVID-19 and Where We Went Wrong*

are in regards to COVID-19 and our country's general misdirected abandonment of COVID-19 infected patients by withholding early treatment (<72 hours from diagnosis) from **all** by not treating **all** with: **Passive Immunization** (e.g.: polyclonal antibodies: COVID-19 or monoclonal antibodies) and, more beneficially, using synergistically **the only** FDA approved antiviral drug **VEKLURY (remdesivir) NDA #21478 (since October 22, 2020)** in the treatment of **COVID-19**:

Public Catalog				
Copyright Catalog (1978 to present)				
Search Request: Left Anchored Name = Andrus Charles H				
Search Results: Displaying 1 through 12 of 12 entries.				
<div> <div>previous</div> <div>next</div> </div>				
<div> <div>Resort results by:</div> <div>Set Search Limits</div> </div>				
#	Name (NALL) <	Full Title	Copyright Number	Date
<input type="checkbox"/> [1]	Andrus, Charles H., 1953-	<a href="#">Correspondence regarding aberrancies in attending surgeon supervision of resident surgeons in the VA.</a>	TXu001288808	2006
<input type="checkbox"/> [2]	Andrus, Charles Harold, 1987-	<a href="#">Ethical issues in "medicine" that touched our family.</a>	TXu001145557	2003
<input type="checkbox"/> [3]	Andrus, Charles Hiram, 1953-	<a href="#">I Dear Mr President PLEASE COVID-19 Convalescent Plasma NOW 11-17-2020.</a>	TXu002232947	2020
<input type="checkbox"/> [4]	Andrus, Charles Hiram, 1953-	<a href="#">Addendum to correspondence regarding the manuscript : Mortality outcomes and attending surgeon presence at the time of operation.</a>	TXu001274328	2005
<input type="checkbox"/> [5]	Andrus, Charles Hiram, 1953-	<a href="#">Correspondence regarding the manuscript Mortality outcomes and attending surgeon presence at the time of operation.</a>	TXu001262126	2005
<input type="checkbox"/> [6]	Andrus, Charles Hiram, 1953-	<a href="#">Mayo Clinic "Safety Update" should be Classified as a Completed Phase I Trial of COVID-19 Convalescent Plasma.</a>	TXu002214049	2020
<input type="checkbox"/> [7]	Andrus, Charles Hiram, 1953-	<a href="#">"Primum non nocere" and practicing ethics in medicine in this era of "the bottom line."</a>	TXu001203831	2004
<input type="checkbox"/> [8]	Andrus, Charles Hiram, 1953-	<a href="#">Rationing of medical care and the election of 2004.</a>	TXu001192071	2004
<input type="checkbox"/> [9]	Andrus, Charles Hiram, 1953-	<a href="#">Time: The Crucial Independent Variable of the COVID-19 Pandemic.</a>	TXu002199029	2020
<input type="checkbox"/> [10]	Andrus, Charles Hiram, 1953-	<a href="#">To care for him who shall have borne the battle, and for his widow, and his orphan.</a>	TXu001196220	2004
<input type="checkbox"/> [11]	Andrus, Charles Hiram 3rd, 1953-	<a href="#">Correspondence from the US Office of Special Counsel in Andrus v. VA and allegations of obstruction of justice / compiled by Charles H. Andrus.</a>	TXu001165703	2004
<input type="checkbox"/> [12]	Andrus, Charles Hiram 3rd, 1953-	<a href="#">To care for him who shall have borne the battle and for his widow and his orphan.</a>	TXu001173542	2004

Much of what I have written and collected over the years regarding the VA and especially regarding the University/VA Attending Surgeon abuse of the key phase contained in VHA Handbook 1400.1, RESIDENT SUPERVISION: "*Level 3: Attending Surgeon Immediately Available, Not Present*" have been submitted as 9 documents from 2003 to 2006 to the U.S. Copyright Office of the Library of Congress for preservation for history. Much of that makes up the vast majority of background documentation contained in draft BOOK 3 which your office was sent by me by U.S.P.S. priority mail on September 24, 2022:

*Dear Mr. President: ...to Care for Him who Shall have Borne the Battle... A. Lincoln*

The other three documents regarding COVID-19 and where the U.S.A. has failed in the early (<72 hours) treatment with immunoglobulins and antivirals of every individual infected with COVID-19 were submitted to the U.S. Copyright Office of the Library of Congress as listed above as #9, #6, #3:

#9 *Time: The Crucial Independent Variable of the COVID-19 Pandemic*, TXu002199029

#6 *Mayo Clinic "Safety Update" should be Classified as a Completed Phase I Trial of COVID-19 Convalescent Plasma*, TXu002214049

#3 1 Dear Mr President PLEASE COVID-19 Convalescent Plasma NOW 11-17-2020, TXu002232947

In mid-June 2020, I received a letter from Kara Harris' office of the U.S. National Institute of Allergy and Infectious Diseases (NIAID) of the U.S. National Institutes of Health (NIH) responding on behalf of Dr. Fauci to my submission (#9), which stated that Dr. Fauci was too busy to look at my submission (#9 above: *Time: The Crucial Independent Variable of the COVID-19 Pandemic*, TXu002199029). In her letter, she established NIH NIAID Case #12276 file – and, thus, for the last three years **ALL** my correspondence has been cc'd to the NIAID and NIH NIAID with Case #12276 is on the front page of the documents. **ALL** that has been submitted to NIH NIAID Case #12276 is, by federal law, legally discoverable by a formal request to office of the NIH NIAID FIOA and Privacy Act Request Coordinator at 301-496-9737 ([nhlbfoiarequest@nhlbi.nih.gov](mailto:nhlbfoiarequest@nhlbi.nih.gov)). [the present FOIA officer is listed as Marianne Manheim, [marianne.manheim@nih.hhs.gov](mailto:marianne.manheim@nih.hhs.gov) ].

Please note Mr. Secretary, as I am a Federal Physician and Surgeon and the claimant of the 12 documents in the U.S. Copyright Office of the Library of Congress, **I waive all my rights regarding those 12 documents** so that anyone can reprint, copy and paste, or quote whatever to whomever they wish. Therefore, if somebody requests under the Freedom of Information Act the contents of NIH NIAID Case #12276, the NIAID can reproduce all without trepidation or concerns anything I have submitted as I have freely waived my claimant U.S. Copyright Office rights. I will submit to your VA office, the office of the VA General Counsel (the DAEO office), and Ms. Harris' Office of the NIH NIAID under NIAID Case# 12276 electronic versions including Books 1, 2, 3 on a 16 Gigabyte SDHC Memory Card which can be copied and distributed (e.g. Micro Center 16 GB SDHC Memory Card (10 Pack) Class 10 USH-I U1 Speed Class) by either the FOIA offices of the VA or the NIH NIAID upon formal request.)



150 Emerald Green Ct  
Creve Coeur (St. Louis), MO 63141  
Home: 314-455-9482  
Pam's phone: 314-809-9634

April 27, 2023

The Honorable Joseph Biden  
President of the United States of America  
c/o The Honorable Denis McDonough  
Secretary, U.S. Department of Veterans Affairs  
[Denis.McDonough@va.gov](mailto:Denis.McDonough@va.gov)  
1600 Pennsylvania Avenue, NW  
Washington, DC. 20500  
202-456-1414

Dear Mr. President:

Please excuse my straightforwardness but having been involved in the Veterans Health Administration of the U.S. Department of Veterans Affairs from April 8, 1982 to November 3, 2022, and as a federal pensioner now under the auspices of the U.S. Office of Personnel Management (OPM), you're still are my boss—so this is my exist interview with my boss: (1) from my VA clinical position as a former Physician and Surgeon, Veterans Health Administration, U.S. Department of Veterans Affairs and (2) an explanation of the >14 lbs of documentation I sent to you on September 24, 2022, USPS Priority mail: 9410 8036 9930 0153 7265 90.

Throughout my professional life, I have tried to the best of my abilities to be a responsible, dedicated, accountable Federal Physician and Surgeon under the auspices of the Veterans Administration (today, Veterans Health Administration [VHA]) in the care of every Veteran patient that presented to me over the last 40 years. On the evening of March 3, 2004, after the oral arguments that day were concluded before the U.S. Court of Appeals for the Federal Circuit in *Andrus v. VA*, Docket # 03-3162, the Andrus family [my two oldest sons (we have five boys: Charlie, Patrick, Thomas, Michael, and Timothy), my wife, Pamela Bergkamp Andrus, and myself, Charles Hiram Andrus, III, M.D., F.A.C.S.] went to the Lincoln Memorial to read the last sentence inscribed on the north inner wall of the Lincoln Memorial:

([https://www.shapell.org/manuscript/abraham-lincoln-with-malice-toward-none-second-inaugural-aqs/?gclid=EAIaIQobChMInvrX3KOz\\_gIVjyyzAB0\\_LAIQEAAAYASAAEgK3avD\\_BwE#transcripts](https://www.shapell.org/manuscript/abraham-lincoln-with-malice-toward-none-second-inaugural-aqs/?gclid=EAIaIQobChMInvrX3KOz_gIVjyyzAB0_LAIQEAAAYASAAEgK3avD_BwE#transcripts)):



"With malice towards none; with  
charity for all; with firmness in  
the right, as God gives us to see  
the right, let us strive on to finish  
the work we are in; to bind  
up the nations wounds; to care  
for him who shall have borne  
the battle, and for his widow  
and his orphan — to do all  
which may achieve and cherish  
a just, and a lasting peace am-  
ong ourselves, and with all na-  
tions."

Abraham Lincoln.

Throughout my professional life as a VA Physician and Surgeon, I have tried to the best of my abilities in my daily practice and interaction with Veteran patients, to do that which President Lincoln admonished all of us to do:

**...to care for him who shall have borne the battle, and for his widow and his orphan... .**

While this interaction with you today is my affirmation and assessment of the forty years of my personal dutiful commitment to the United States of America (USA), it was and is my continued response to our collectively-mandated commitment to the rights of all individual Veteran patients to good and appropriate healthcare through the words of President Lincoln directed by the United States of America. Truthfully, this commitment should not only be for Veteran patients but all individuals of the USA. Over the last 40 years, I have witnessed bureaucratic intolerance, obfuscation, misdirection, and misinterpretation of the intent of federal laws; political arrogance and greed, and, most of all, self-serving stupidity towards our fellow man that unnecessarily led to increased morbidity and mortality of Veteran patients and all Americans in general. For my continued fulfillment to my duty to our country as a Federal Physician and Surgeon, on September 24, 2022, I sent to you >14 lbs of rough-draft documentation by U.S.P.S. priority mail (USPS Priority mail: 9410 8036 9930 0153 7265 90) in three books (draft collections in approximately chronological order) entitled:

Book 1: *Dear Mr. President: COVID-19 and Where We Went Wrong*

Book 2: A cover letter to Secretary McDonough with supporting material regarding the bureaucratic obfuscation and stupidity that resulted in my erasure from the history of the Edward Hines, Jr. VAH and my becoming an “unperson” in the records of the U.S. National Archives

Book 3: *Dear Mr. President: “...to care for him who shall have borne the battle...” A. Lincoln.*

U.S. Postal Service as Priority Mail to: the US Department of Veterans affairs (offices of the Secretary of the Department of Veterans Affairs [USPS tracking number: 9410 8036 9930 0153 7266 20], the offices of the General Counsel (and DEAO) per the direction of Michael Hogan, J.D. in our phone conversation in the Spring of 2022 to copy all to the OGC [USPS tracking number: 9410 8036 9930 0153 7266 06]); The National Institute of Allergy and Infectious Diseases as per the establishment of NIAID Case file #12276 [accessible to anyone under the FOIA] by Kara Harris MPH [USPS tracking number: 9410 8036 9930 0153 7286 24] at the direction of the Director, Anthony Fauci, M.D. [USPS tracking number: 9410 8036 9930 0153 7266 13]; and the U.S. Constitutional-responsible and accountable authority for the Executive Branch of the Federal Government, President Joseph Biden [USPS tracking number: 9410 8036 9930 0153 7265 90] and others.

Mr. President, in short, we as a nation are continually misleading ourselves and our society by **Sins of Omission** (telling half-truths by withholding pertinent details), employment of obfuscating **Euphemisms** (see George Carlin’s HBO presentation over 3 decades ago: <https://www.youtube.com/watch?v=isMm2vF4uFs>), and justifying these half-truths before society and our minds by the syndrome described in the Medical literature as **Chronic Denial** (Attachment **0.84 1977 Gilman letter Yale University New Haven.pdf**).

Today, it is common place to *Lie with Statistics* ([https://online225.psych.wisc.edu/wp-content/uploads/225-Master/225-UnitPages/Unit-07/Huff\\_StatisticsBook\\_1954.pdf](https://online225.psych.wisc.edu/wp-content/uploads/225-Master/225-UnitPages/Unit-07/Huff_StatisticsBook_1954.pdf)). All Departments of the Executive Branch of the U.S. Federal Government have gotten extremely proficient at (1) electronic overwriting and (2) changing officially-named document titles and thus URLs to render the past history of a U.S. government document relatively, legally non-discoverable requiring an exact knowledge of the precise URL and then necessitating a reviewing through the Wayback Machine of the Internet Archive which is a non-governmental, not-for-profit Internet Archive tool: <https://archive.org/web/>. If one wants to really cover-it-up / loose the document as non-discoverable, one need only change the title of the document (e.g. VHA Handbook 1400.1 to VHA Handbook 1400.01) and the latest URL may no longer be

similar to the previous URL so that discovery of previous versions of a federal document through the Wayback Machine are virtually impossible! An example of the morphing process to **COVER-UP corrections of previous versions that are NOT discoverable** in the VHA Handbook RESIDENCY SUPERVISION Directive over time are examples of legal obfuscation / essentially non-discoverability by overwriting and changing URLs:

- (1) VHA 1400.1 RESIDENT SUPERVISION, October 25, 2001, URL:  
[http://web.archive.org/web/20041028182959/https://www.va.gov/oaa/1400\\_1hk\\_Oct2001.doc](http://web.archive.org/web/20041028182959/https://www.va.gov/oaa/1400_1hk_Oct2001.doc);
- (2) VHA 1400.01 RESIDENT SUPERVISION, December 19, 2012:  
[https://www.va.gov/OPTOMETRY/docs/VHA\\_Handbook\\_1400-01\\_Resident\\_Supervision\\_12-19-2012.pdf](https://www.va.gov/OPTOMETRY/docs/VHA_Handbook_1400-01_Resident_Supervision_12-19-2012.pdf) ; and
- (3) VHA 1400.01 SUPERVISION OF PHYSICIAN, DENTAL, OPTOMETRY, CHIROPRACTIC, AND PODIATRY RESIDENTS, November 7, 2019:  
[https://www.va.gov/OPTOMETRY/docs/1400\\_01\\_D\\_20191107.pdf](https://www.va.gov/OPTOMETRY/docs/1400_01_D_20191107.pdf)

During COVID-19, the FDA, the NIH, the CDC, the VHA, etc. demonstrated their understanding, proficiency, and mastery of these QUESTIONABLE, governmentally-condoned methodologic technics of obfuscation in all aspects of our lives over the last three years during the American COVID-19 epidemic. Most importantly, in the FDA'S, NIH'S, etc's overwhelming short-sighted promotion of:

- (1) only **prophylaxis (Active Immunization)** (e.g. with mRNA vaccines) with the subsequent development of **endogenous antibodies**: i.e.: non-infected individuals responding to the production of IgG to the vaccines); and
- (2) in deference to **treatment** within 72-120 hours of the contraction of the virus (becoming infected) **TO EVERY INDIVIDUAL AMERICAN** who contracted SARS-CoV-2 by the individual with **TREATMENT** with **Passive Immunization**: COVID-19 Convalescent Plasma, monoclonal antibodies, monoclonal antibody cocktails, etc. and, most importantly synergistically, with available **antivirals**. (i.e.: Remdesivir under an EUA from May 1, 2020 and subsequently as the FDA approved prescription drug, VEKLURY, NDA# 214787 since October 22, 2020  
[https://www.accessdata.fda.gov/drugsatfda\\_docs/applletter/2020/214787Orig1s000ltr.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/applletter/2020/214787Orig1s000ltr.pdf), and now more recently with Paxlovid which is still under an EUA since December 22, 2021.  
<https://web.archive.org/web/20211222180424/https://www.fda.gov/media/155049/download> )

Mr. President: Why is the previous paragraph so important? As a retired federal-physician, I will receive a pension (hopefully recalculated) through the Office of Personnel Management (OPM) for the rest of my life as with every other federal employee under the Federal Employee Retirement System (FERS). For example, unlike me who bureaucratically was "lost" by the VA with the VA not yet able to appropriately calculate correctly my past gross pay for the last six years and consequently my federal pension for the rest of my life, Anthony Fauci, M.D., is scheduled to receive a purported tremendous federal pension based on the average of his top three consecutive salaries which will approximate or may surpassed your annual salary of \$400,000 which is supposed to be the "salary cap" of all federal employees.



As you are the U.S. Constitutionally-documented administrator and top executive of the Executive Branch of the U.S. Federal Government, Mr. President, **YOU ARE THE BOSS** of all federal employees--both those continuing in employment in the agencies and departments of the Executive Branch of the Federal Government and those retired pensioners, like Dr. Fauci and myself, paid under the Office of Personnel Management (OPM).

The expression: "Follow the Money" is attributed to Mark Felt's character *Deep Throat* in *All the President's Men*. Mr. President, in regards to the tragedy (>1.1 million dead and many more maimed) of the U.S. misguided *de facto* patient abandonment of COVID-19 infected individuals by withholding early treatment (<72 hours from diagnosis) (or giving it too-late during the Cytokine Cascade and the Bradykinin Storm of COVID-19 pathophysiology), **Passive Immunization** and, synergistically with **antivirals**, was the *sine qua non* of the U.S.A's collective approach in those that were infected with COVID-19. Mr. President, have your advisors coordinate for you the **addressing of the lies of omission** of all federal physicians, U.S. Medicine in general, and the medicine-federal-pharmaceutical industrial complex by following the money! (See Attachment VII SINS OF OMISSION 2022-09-05 Dear Mr. President.pdf)

If you find my assertions hard to believe, as I am still a salaried physician through OPM and therefore **you are my boss**; and, thus, it is my duty to suggest to you that you pose the question to your federal physician advisors in U.S. government employment (both active and retired) the traditional Yes/No dilemma of the rhetorical "loaded question":

**Yes or No: When are you going to stop lying to the me and the American people?**

On September 24, 2022, I sent to you >14 lbs of supportive documentation by U.S.P.S. Priority Mail (USPS Priority mail: 9410 8036 9930 0153 7265 90), so that the physician advisors of both President Trump and yourself regarding COVID-19 (e.g.: Fauci, Collins, Birks, Redfield, Hahn, Marks, , etc. could honestly discuss the complexities of the pathophysiology of COVID-19; the clinical immunotherapy difference between prophylactic vaccination of non-actively-infected individuals only (endogenous immunotherapy by **Active Immunization**) versus early treatment (<72 hours from diagnosis) with **Passive Immunization** and synergistically, **antivirals**.

As those in the FDA and NIH over the last three years took little heed (really no heed) of my message of going back to the foundational basics of clinical immunology, I doubt whether they will now. If you wish to discuss that which I have outlined in this submission (or in more detail, the >14 lbs of documentation I sent to you on September 24, 2022 by U.S.P.S. Priority Mail) and the multifaceted implications of this documentation going forward regarding our country's future please do not hesitate to call upon me. If you so desire, I will be very happy to debate before you, the foundational concepts of appropriate clinical early treatment (<120 hours from diagnosis) for the individual patient infected with the next novel virus like COVID-19 with **Passive Immunization** and synergistically with **antivirals** (when available) which has been the mainstay of the clinical TREATMENT APPROACH of infected individuals for at least a century. (i.e.: Emil von Behring in his work regarding **Passive immunization**) was awarded the first Nobel Prize in Medicine or Physiology in 1901.

<https://www.nobelprize.org/prizes/medicine/1901/behring/biographical/>

Mr. President, I'm just a General Surgeon who recalls the clinical immunologic fundamentals that he was taught regarding **Active Immunization** versus **Passive Immunization** at Saint Louis University (SLU) Medical School [the Dean euphemized the school's name to SLU School of Medicine (SLUSOM) so as not to use the school's previous initials: SLUMS]. In my mailing to you to follow via U.S.P.S. priority mail, I will enclose a copy of the 7<sup>th</sup> edition of Dr. Plotkin's textbook in my mailing to you so you might read Chapter 8.:

Plotkin SA, Orenstein WA, Offit PA, Edwards KM: *Plotkin's VACCINES*. Mr. President, please read Chapter 8: Mark K. Slifka and Ian J. Amanna: *Passive Immunization*, pages 84 – 95.  
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7151993/pdf/main.pdf>

Mr. President, please look at Figure 8.2 and the caption regarding the efficacy of passive immunity decreasing disease progression on page 88. That one figure graphically discounts everything that was done WRONG in the providing and rationing COVID-19 Convalescent Plasma, monoclonal antibodies, or monoclonal antibody cocktails late in the pathophysiology of the SARS-CoV-2 disease during the Cytokine Cascade and the Bradykinin Storm as the immunotherapies would have been (and still would be if new monoclonal antibodies were developed after each COVID-19 mutation shift) most effective during the initial viremia (with 72 hours of diagnosis) in ALL individuals infected with COVID-19.

This week, *The New-York Times* reporter David Wallace-Wells reported on his interview of Dr. Fauci entitled: “Dr. Fauci Looks Back: ‘Something Clearly Went Wrong’”  
<https://www.nytimes.com/interactive/2023/04/24/magazine/dr-fauci-pandemic.html> . In an answer to Mr. Wallace-Wells question: “Do you think the experience of the pandemic – and the possibility of a lab origin, however remote—should change how we think about the risks and benefits of this entire field of research?” While the rest of Dr. Fauci's response speaks about the euphemism of gain-of-function research which amounts to an issue of distraction, the first sentence is a truism that all of U.S. Medicine, the U.S. Pharmaceutical Industry, and U.S. Government failed miserably to follow throughout the last three years:

You have to have a totally transparent process that involves scientific input and community input – informed community input.

Dr. Fauci did not listen (and implement in the “community”) to the advice of Michael Joyner, M.D., Deborah Birx, M.D, or Arturo Casadevall, M.D. regarding early treatment (<72 hours from diagnosis) of the SARS-CoV-2 infection of the individual patient with COVID-19 Convalescent Plasma. When I wrote of our (U.S. Medicine) approach of discounting appropriate early (<72 hours from diagnosis of COVID-19 infection) of treatment with **Passive Immunization** in *Time: The Crucial Independent Variable of the COVID-19 Pandemic*, TXu002199029, Dr. Fauci responded to me through Kara Harris, MPH establishing NIAID Case #12276 with:

Thank you for your recent fax directed to Anthony S. Fauci, M.D., director of the National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health. Due to his professional responsibilities, Dr. Fauci has asked me to respond on his behalf.

**0.99 Attachment VIII NIH and FDA responses including 6-10-2020 re NIAID Case #12276.pdf**

Dr. Fauci was too busy to listen when in the prose of TXu002199029, I drew the analogy of withholding appropriate early treatment (<72 hours from diagnosis of COVID-19 infection) with COVID-19 Convalescent Plasma of COVID-19 was analogously tantamount on a national level



to the withholding of penicillin in the Tuskegee Syphilis Study (“Tuskegee study of untreated syphilis in the Negro Male”) in the mid-twentieth century. On May 16, 1997, President Clinton apologized to the eight surviving Alabama share-croppers and approximately ~600 others who had died <https://clintonwhitehouse4.archives.gov/New/Remarks/Fri/19970516-898.html> President Biden, why don’t you phone President Clinton and ask him specifically what were his emotions when he delivered this apology for to those survivors on behalf of U.S. Medicine and our nation.

For that matter, Mr. President, we continue to fail to listen to and learn from history and minimize informing “the community”: e.g.:

- (1) Emil von Behring and his descriptions of antitoxins and Louis Pasteur and the rabies vaccine;
- (2) gamma globulin (the forerunner of IVIG)--utilized by a young NIAID hepatitis researcher in the late 1940s, James William Colbert, Jr., M.D. Mr. President, could you image if Dr. Fauci had alluded to the fact that Dr. Colbert had used gamma globulin (*Passive Immunization*) in the treatment of serum hepatitis at the NIAID in his interview with Dr. Colbert’s son, Stephen, last fall?  
<https://www.youtube.com/watch?v=PEOm5QhJVIE>; and
- (3) in an interview by Dr. Morrissey of *The New England Journal of Medicine* in 2018 regarding then a recent review publication: Marston HD, Paules C, **Fauci AS**: Monoclonal antibodies for emerging infectious diseases – Borrowing from history. **N Engl J Med** 2018 Apr 19; 378 (16): 1469 – 1472.  
[https://www.nejm.org/doi/10.1056/NEJMp1802256?url\\_ver=Z39.88-2003&rft\\_id=ori:rid:crossref.org&rft\\_dat=cr\\_pub%20%200pubmed](https://www.nejm.org/doi/10.1056/NEJMp1802256?url_ver=Z39.88-2003&rft_id=ori:rid:crossref.org&rft_dat=cr_pub%20%200pubmed) , in which Dr. Fauci stated in response to Dr. Morrissey:

*Dr. Morrissey:* You write in your article that several antibody therapies have been licensed for infectious diseases. What have researchers learned from the development of those therapies and for more recent attempts to create monoclonal antibodies against—say-- Ebola or Zika?

**Dr. Fauci:** Well, for example, a classic monoclonal antibody for prophylaxis against **Respiratory Syncytial Virus** has been developed with considerable success. We began thinking very intensively about this just literally over the past few years when we in rapid succession had to confront both the Ebola outbreak followed by the Zika outbreak. ...

Yes, Mr. President, since 1998, SYNAGIS (palivizumab) BLN 1252 has been an FDA approved-prescription monoclonal antibody in the prophylaxis and early treatment of Respiratory Syncytial Virus (RSV) **only** in high-risk infants. The CDC suggests that while there are 100 – 300 deaths in children less than 5 years of age annually, there are 6,000 - 10,000 adult deaths over 65 years of age annually.  
<https://www.cdc.gov/rsv/research/index.html#:~:text=58%2C000%2D80%2C000%20hospitalizations%20among%20children%20younger%20than%205%20years%20old.&text=60%2C000%2D160%2C000%20hospitalizations%20among%20adults%2065%20years%20and%20older.&text=6%2C000%2D10%2C000%20deaths%20among%20adults%2065%20years%20and%20older.>

So why has the FDA directed rationing of the access to this FDA approved prescription monoclonal antibody for a quarter of a century instead of encouraging production and stockpiling over the last quarter of a century for **Passive Immunization** by early treatment (<72 hours from diagnosis) for all ages who become infected with RSV?

- (4) Mr. President, on April 10, 2023, you signed into law PL-118-3 (H.J. Res. 7) <https://www.congress.gov/bill/118th-congress/house-joint-resolution/7> which rescinds President Trump's Executive Order 9994 of March 13, 2020 which declared the COVID-19 epidemic in the United States of America a Public Health Emergency (PHE). Mr. President, how are all the COVID-19 home tests and antivirals like Paxlovid going to be available as they are "FDA authorized—Emergency Use Authorization (EUA) and not FDA approved like the antiviral VEKLURY (remdesivir)? Anything that was FDA-authorized under the umbrella of an EUA during the PHE will revert to FDA status of Investigational / Experimental. Most malpractice carriers proscribe physicians under their coverage from prescribing investigational /experimental drugs or treatments without being IRB approved investigators involved in a research protocol.

Mr. President, I am just an American Board of Surgery-certified, insignificant, unknown federal physician and general surgeon of the Midwest who the VHA has officially denied even my existence between April 8, 1982, and January 22, 2002, for the last two decades before itself and the U.S. National Archives. (Mr. President, I, like Dr. Fauci, was trained by the Jesuits and self-deprecation can be a very forceful methodology in *Reductio ad Absurdum* – that is, reduce the argument to the absurd. (Please read at least the title page of: **0.1 2023-04-27 Tale of Two Presidents**) Mr. President, in my mind, I have always tried to serve our country—to the best of my ability--at the pleasure of the President of the United States. If I can be of assistance to you, please call me: 314-455-9482—my home, 314-265-1814—my cell, or, most especially, 314-809-9634—Pam's cell which is the most reliable as we tomorrow will be leaving for San Francisco to visit my home city including those sites that were instructionally foundational to me: St. Gabriel's Parish and School, St. Ignatius College Prep, and the University of San Francisco.

Mr. President, thank you very much for considering this submission.

Respectfully,

Charles H. Andrus, M.D., F.A.C.S.

Retired VHA Physician and Surgeon, U.S. Department of Veterans Affairs (1982 – 2002 and 2016 – 2022)

Former Professor, Department of Surgery, Saint Louis University SOM (2006-2022) and

Former Professor and Vice-Chairman, Department of Surgery,

Loyola University (Chicago) SOM and Chief, Surgical Services, Edward Hines, Jr. VAH (1996-2002)



## Table of Contents of the electronic submission of April 28, 2023

(Abridged not containing folder BOOKS 1\_2\_3, folder 0.99 Bibliographic Timelines, and some VA RSSO documentation Nov 2022 to March 2023.)

## The subsequent full submission by U.S.P.S. Priority Mail on a 16 Gigabyte disk

2023-04-21 final			
Back/Forward			
View Group Share Edit Tags Action Search			
2023-04-21 final			
Name	Date Modified	Size	Kind
0.0 2023-04-27 Thank you letter to Mr. Stubbs .pdf	Yesterday, 9:11 PM	802 KB	PDF Document
0.0 2023-04-27 Thank you letter to Mr. Stubbs (to send in e-mail to Mr. Stubbs)	Yesterday, 9:07 PM	3.4 MB	Microsoft Word document (.docx)
0.0 Table of Contents of submissions April 27-28 2023.pdf	Today, 8:16 AM	425 KB	PDF Document
0.1 2023-04-28 Tale of Two Presidents.pdf	Today, 8:04 AM	833 KB	PDF Document
0.2 2022-09-11 Dear Mr. President Case Report and COVID-19 pathophysiology.pdf	Yesterday, 6:17 AM	2.4 MB	PDF Document
0.3 Attachment I Andrus SLU cv 8_11_2021.pdf	4/25/23, 8:12 PM	651 KB	PDF Document
0.4 Attachment II SF-50s including 01-19-2002 45.remarks Constructive Discharge.pdf	4/26/23, 1:26 PM	2.2 MB	PDF Document
0.5 Attachment III 2023-04-18 Andrus recalc of pay and pension.xlsx	4/25/23, 12:06 PM	20 KB	Microsoft Excel Workbook (.xlsx)
0.6 NOT IN E-MAIL Attachment IV 2023-02-13 VA RSSO 120 SE 6th suite 102 Topeka_KS.pdf	Yesterday, 5:36 AM	9.1 MB	PDF Document
0.7 Attachment V 2023-01-29 cover Andrus e-mail transmission to VA.pdf	Yesterday, 5:39 AM	252 KB	PDF Document
0.80 Attachments VI Email correspondence re D...wley involvement in VA-University affiliation.pdf	4/25/23, 8:24 PM	109 KB	PDF Document
0.81 Chapter 3 The Dog Lab.pdf	4/26/23, 1:22 PM	273 KB	PDF Document
0.82 14 Chapter 14 Discussions and Reflections.pdf	4/26/23, 1:21 PM	1.2 MB	PDF Document
0.83 2006_06_18-Whatever_you_say_Doc.pdf	4/25/23, 8:30 PM	1.3 MB	PDF Document
0.84 1977 Gilman lettter Yale University New Haven.pdf	4/25/23, 8:45 PM	597 KB	PDF Document
0.90 Attachment VII SINS OF OMISSION 2022-09-05 Dear Mr President.pdf	Yesterday, 6:04 AM	255 KB	PDF Document
0.99 Attachment VIII NIH and FDA responses including 6-10-2020 re NIAID Case #12276.pdf	4/26/23, 1:19 PM	1.1 MB	PDF Document
0.99 Bibliographic Timelines	Today, 7:59 AM	--	Folder
10 2022-05-30 Bibliographic Timeline References Microsoft Word copy 2	8/24/22, 4:04 PM	363 KB	Microsoft Word document (.docx)
20 2022-05-30 annotated Bibliographic Timeline References Microsoft Word copy 2	3/21/23, 5:40 AM	59 MB	Microsoft Word document (.docx)
BOOKS 1_2_3 and some VA RSSO documentation Nov 2022 to March 2023	4/26/23, 12:41 PM	--	Folder
20.0 VA RSSO over last 6 months copy	3/13/23, 8:27 AM	--	Folder
40.1 2023-02-25 to send by e-mail to OPM FOIA	3/14/23, 10:03 AM	--	Folder
BOOK 1 Dr Mr President..COVID-19 and Where we went Wrong 2023-02-02 copy.pdf	2/2/23, 3:52 PM	109.9 MB	PDF Document
Book 2 combined pdf VA submission of 9-24-2022 copy.pdf	1/24/23, 3:04 PM	63.4 MB	PDF Document
Book 3 2023-01-19 Dear Mr President. ...To ca...r him who shall have borne the battle copy.pdf	2/9/23, 4:28 PM	570.5 MB	PDF Document





# ***Reductio ad Absurdum*<sup>1</sup>**

## **The COVID-19 Tale of Two Presidents, the Ramifications of Fifty Years of American Scandal, Therapeutic Nihilism, and Medical Stupidity:**

**Euphemisms**<sup>2</sup>: Experimental / Investigational / EUA<sup>3</sup>,  
Expanded Access<sup>4</sup> / Compassionate Care  
FDA Authorization vs FDA Approval<sup>5,6</sup>,  
Treatment vs Prophylaxis<sup>7</sup>,  
Active Immunization<sup>8-9</sup> vs Passive Immunization<sup>10,11</sup>, etc.,

**FDA Archiving reliance on non-governmental sites**<sup>12,13</sup>

FDA archived web material [is](#) maintained within the Pagefreezer platform.

and loss of information by *electronic overwriting* and *destruction* of URLs<sup>14-16</sup>,

**FDA and NIH blatant, total disregard** of the Right to Try Act (PL-115-176)<sup>17</sup> by  
never declaring a completed Phase 1(Safety) [vs Phase 2/3 Efficacy]  
Clinical Trial<sup>18-24</sup> and thus dismissing and *de facto* legally violating PL-115-176<sup>17</sup>

**Statistical Misdirection**<sup>25-28</sup>,

**Predatory Marketing**<sup>29</sup>, and

**> 1.1 million Americans dead**<sup>30</sup> associated with withholding early (within 72-  
120 hours of diagnosis) synergistic treatment with **Exogenous Immunoglobulins**  
**(Passive Immunization)**<sup>10,11</sup> and **Antivirals**<sup>31</sup>

**Contingent on**: Ignorance<sup>32</sup>, Sins of Omission<sup>33-34</sup>, Conflicts-of-Interest<sup>35-36</sup>, Greed<sup>37</sup>

***“Reform must come from within, not from without.  
You cannot legislate for Virtue”***<sup>38</sup>

James Cardinal Gibbons, “Prince of Democracy”<sup>39</sup>

Charles H. Andrus, M.D., F.A.C.S.<sup>40</sup>  
Former Physician and Surgeon, Veterans Health Administration  
U.S. Department of Veterans Affairs  
**U.S. National Institute for Allergy and Infectious Diseases (NIAID) Case# 12276**  
150 Emerald Green Court, St. Louis, MO 63141  
Home phone: 314-455-9482, Cell: 314-265-1814  
April 26, 2023 (Draft article for Educational Purposes only)

## Introduction:

A Century ago, the United States of America addressed monumental sociopolitical medical evils like:

The Spanish Flu Epidemic of 1918 with *Passive Immunization (Convalescent Plasma)*<sup>41-43</sup>;

Substandard Medical Schools with the Flexner Report (1914)<sup>44</sup>;

Generally deplorable medical care in hospitals by oversight of the American College of Surgeons (1913)<sup>45</sup>;

Tainted foods and medical quackery with the establishment and empowerment of the U.S. Food & Drug Administration (FDA)<sup>46</sup>.

In this new millennium, some of our foundational intents and tenets have been subjected to the misapplication of the Golden Rule<sup>47</sup>: “*Do unto others as you would have them do unto you*” that have evaded and, in some instances, besmirched and discarded ethical principles we uniformly profess during the World’s confrontation with coronavirus, SARS-CoV-2, COVID-19 Pandemic!<sup>48</sup>

Originating during the Winter of 2019 in Wuhan, China<sup>49</sup>, a global epidemic (pandemic) arose due to the coronavirus, SARS-CoV-2 which overwhelmed the medical response around the world. In a television summary interview of the previous eighteen months of the COVID-19 pandemic airing on the Columbia Broadcasting System (CBS)’s *Face the Nation*<sup>50</sup> on November 28, 2021, the interviewer, Margaret Brennan<sup>51</sup>, queried and Dr. Anthony Fauci, M.D.<sup>52</sup>, Director of the National Institute of Allergy, responded:

MARGARET BRENNAN: But just to button that up. Why aren't we having a national conversation about what went wrong? I mean, apart from this room right now, why isn't there a 9/11 type commission?

DR. FAUCI: Yeah, I think what's going to happen is that you are going to see that for sure, MARGARET. I think the lack of doing that now is because you're focusing on getting this thing under control. I would be astounded if we didn't have a very serious look at what went right, what went wrong, from a public health standpoint, from a local standpoint, from a global standpoint. I don't think that the public should imagine that this is going to go through with already 760,000 Americans dying and 40 plus million at least being infected, close to six million people globally dying. **And we're not going to look back at this and tear it apart, examine it, do an autopsy on it and try and figure out. So people should not think that that's not going to happen. It's not happening now because everybody's focusing on getting this thing under control.**

Ms. Brennan’s suggestion of a 9/11 type commission and Dr. Fauci’s concurrence never materialized. Dr. Fauci’s analogy of an autopsy—which is, by the *autopsy*’s very nature, a gross anatomic investigation of the discreet, individually unique dead body—falls far short of detailed analyses of > 1.1 million deaths in the aggregate.<sup>30</sup> Critical to the story-line of a fictional murder mystery in literature, the autopsy is an integral part of every murder investigation assisting in clarifying and elucidating the **Means, Motive, and Opportunity** of any alleged perpetrator.<sup>53</sup> While the coronavirus SARS-CoV-2 causing the viral disease COVID-19 is a non-sentient entity, from late 2019 to the present, coronavirus SARS-CoV-2 has been the *teleological real-life viral murderer* of greater than 1.1 million infected individuals in the COVID-19 epidemic

of the United States of America. Thus, the coronavirus SARS-CoV-2 murderer had the **Means**, **Motive**, and **Opportunity** to ravage the people of the United States of America and the World:

**Means:** The Pathophysiology of the coronavirus SARS-CoV-2<sup>55-61</sup>:

1. Biochemical and physical characteristics of the virion:
  - a. An enveloped, positive-sense, single-stranded RNA virus of ~30 kb
  - b. A highly-communicable respiratory 80 – 120 nm in-size-viral-particle<sup>62</sup> which can traverse an N95 mask<sup>63</sup> 5% of the time (N95 means the mask will stop particles <300 nm in size 0.95 (95%) of the time)
  - c. While only  $\alpha$  and  $\beta$  genera (of the four coronavirus  $\alpha$ ,  $\beta$ ,  $\delta$ , and  $\gamma$  genuses) of coronaviruses infect mammals, human  $\alpha$  coronavirus (as with 229E and NL63) are responsible for the common cold and croup, SARS-CoV, Middle East respiratory syndrome coronavirus (MERS-CoV) and SARS-CoV-2 are classified  $\beta$  coronaviruses
  - d. Angiotensin Converting Enzyme 2 (ACE2) of the cell is the functional receptor for subunits on the Spike protein of SARS-Cov-2 virion<sup>64-69</sup>
  - e. Markedly increased annual mortality<sup>70</sup> of 0.69 % mortality increase / year past the age of ~fifty:  
$$0 - 45 \text{ years} \quad \text{Mortality rate (y)} = 0.0004 (x) - 0.0023 \quad r^2 = 0.80$$
$$46 - 90 \text{ years} \quad \text{Mortality rate (y)} = 0.0067 (x) - 0.2647 \quad r^2 = 0.80$$
2. Life cycle of the virion:
  - a. Attachment
  - b. Penetration
  - c. Biosynthesis
  - d. Maturation
  - e. Release
3. Epidemiology: Long-term persistence in the United States with an initial epidemic stage of ~3 years and a predictable endemic stage of 9 centuries by the analysis of the logarithmic decay of the initial herd immunity plot over time.<sup>71-74</sup>
4. Virion Darwinistic mutability<sup>75</sup> that sustains the virion by variability with resistance to previously acquired endogenous immunity by vaccination (Active Immunization) or previous contraction(s) of the disease.

**Motive:**

1. Infection of human hosts, highly-contagious respiratory spread, and infection of additional human hosts
2. Virion self-preservation / survival and continued Virion reproduction

**Opportunity / (Impediments) for the VIRUS:** For the coronavirus' *ability to infect the individual patient, cause systemic disease, and result possibly in the infected individual patient's death*, the coronavirus SAR-CoV-2 has:

1. **Intrinsic Opportunities / (Impediments) FOR THE VIRUS murderer** within the individual patient:
  - a. Opportunities for the VIRUS:

- i. In 2020, novel to the human race meaning that the human race was *immunologically naïve* to the coronavirus, SARS-CoV-2 that caused COVID-19
    - ii. A highly communicable respiratory virus with a very small size (80 – 120 nm) and thus there is no absolute “antiviral” impermeable masks as N95 masks permit 5% of all particles <300 nm to traverse the mask.
    - iii. Attaches to the cell via the ACE2 receptor and affects the patient’s intrinsic Immunologic system and the Renin-Angiotensin-Aldosterone system (RAS):
      - 1. During viremia (0 to ~ 7 days) initially as a bilateral pneumonia and
      - 2. During the later phases of the severe systemic disease of cytokine cascade<sup>76-78</sup> (*treated with steroids*) and bradykinin storm (*no known treatment*)<sup>64-69</sup>
    - iv. Progression within 10 days of coronavirus SARS-CoV-2 infection to the later phases of the COVID-19 disease activation of the cytokine cascade and increase in bradykinin production prior to full systemic immunological development of Immunoglobulin G (IgG)<sup>60</sup>
  - b. Impediments to the VIRUS:
    - i. Previous contraction/infection of coronavirus, SARS-CoV-2 with the individual patient’s development of plasma cells to produce polyclonal antibodies to the specific coronavirus, SARS-Cov-2 variant or group of variants
    - ii. The individual’s immune system’s development of endogenous immunoglobulins systemically:
      - 1. By contraction (infection of the individual) of COVID-19 and development of IgM, IgG, and IgA (IgA in the nasopharynx) to a specific variate.
      - 2. Prophylaxis of the entire population with mRNA vaccines to stimulate in each individual endogenous plasma cells producing monoclonal IgM and IgG antibodies only to a specific variant or variants
- 2. **Extrinsic Opportunities / (Impediments) FOR THE VIRUS MURDERER** from outside the individual patient:
  - a. Opportunities for the VIRUS:
    - i. **Uniform LACK of Universal Provision by U.S. Medicine and the Federal Government (*de facto rationing and patient abandonment to every infected untreated individual*) with Early Treatment (<120 hours) with antivirals and exogenous immunoglobulins: COVID-19 Convalescent Plasma, monoclonal antibodies, and monoclonal antibody cocktails**

- ii. A highly communicable respiratory virus with a very small size (80 – 120 nm) and thus there is no absolute “antiviral” impermeable masks as N95 masks permit 5% of all particles <300 nm to traverse the mask.
- iii. Attaches to the cell of the infected patient via the ACE2 receptor and affects the Renin-Angiotensin-Aldosterone system (RAS), e.g.: During viremia (0 to ~ 7 days) as a bilateral pneumonia and during the later phase of severe systemic disease of cytokine cascade and bradykinin storm
- iv. Progression within 10 days of coronavirus SARS-CoV-2 infection to the later phases of the COVID-19 disease activation of the cytokine cascade and increase in bradykinin production prior to full systemic immunological development of Immunoglobulin G (IgG)
- v. Development of resistance to the monoclonal antibodies and the electronic overwriting by FDA so all will be forgotten by history; and the discontinuation by the Pharmaceutical Industry of development of ongoing new monoclonal antibodies (and cocktails).
- vi. Development of new variants resistant to the mRNA vaccines that have already been developed and implemented.
- vii. **Research grant funding and inappropriate statistical methodologies of the FDA, the NIH, BARDA, etc.:**
  - 1. Requiring mandatory placebo-controlled Clinical Trials when case-control clinical trials would have sufficed) –***That is UNETHICAL;***
  - 2. Publishing underpowered, skewed, statistically inappropriate “research” condoned by the FDA, the NIH, *The New England Journal of Medicine*, etc. —***That is just plain STUPID*** e.g.: *SIREN C3PO clinical trial*, NIH NCT04355767
  - 3. the denial and uniform lack of implementation by the FDA and the NIH of adherence to the Right to Try Act (PL-115-176) – **THIS IS REPREHENSIBLE** for federal agencies to violate the intent of the law!
- viii. **Pharmaceutical Industrial short-sightedness and corporate greed**
- ix. **The partisan mentality pervasive in our society**
- x. **The sheer ignorance, meanness, immorality, etc. of the Trump administration**
- xi. Ignorant, uncomprehensible “compromise” that denies foundational scientific knowledge / logic, e.g.: the Supreme Court rulings of January 13, 2022, regarding requiring mandatory masks and vaccinations is **TANTAMOUNT TO SPLITTING THE CHILD IN HALF as posed by Solomon (1 Kings 3:16-28):**  
<https://rollcall.com/2022/01/13/supreme-court-blocks-vaccine-or-mask-mandate-for-larger-employers/> ,  
<https://s3.documentcloud.org/documents/21178592/21a244-21a247.pdf> ,  
<https://s3.documentcloud.org/documents/21178591/21a240-21a241.pdf> , and  
<https://www.biblegateway.com/passage/?search=1%20Kings%203%3A16-28&version=CEV> and  
<https://reason.com/2018/01/20/split-the-baby-drink-the-poiso/> .

b. Impediments to the VIRUS:

- i. Early treatment (0 – 120 hours from diagnosis of the disease) with:



1. Endogenous Immunoglobulins (Passive Immunization):
  - a. COVID-19 Convalescent Plasma – If given within 72 – 120 hours, is effective, e.g.:  
<https://www.nejm.org/doi/full/10.1056/nejmoa2031893>
  - b. Monoclonal Antibodies and monoclonal antibody cocktails (**the new variants of SARS-CoV-2 became resistant to the exogenous antibodies and the FDA has covered this up by electronic overwriting:**
2. Antivirals
  - a. VEKLURY (Remdesivir) NDA 214787, [a nucleotide prodrug of an adenosine which binds to the viral RNA dependent RNA polymerase and inhibits viral replication by terminating RNA transcription prematurely.], is **the only FDA approved antiviral** against COVID-19;  
  
This new drug application provides for the use of VEKLURY (remdesivir) injection, and VEKLURY(remdesivir) for injection, for adults and pediatric patients (12 years of age and older and weighing at least 40 kg) for the treatment of coronavirus disease 2019 (COVID-19) requiring hospitalization. VEKLURY should only be administered in a hospital or in a healthcare setting capable of providing acute care comparable to inpatient hospital care.  
[https://www.accessdata.fda.gov/drugsatfda\\_docs/appletter/2020/214787Orig1s000ltr.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2020/214787Orig1s000ltr.pdf)
  - b. PAXLOVID (nirmatrelvir [a SARS-CoV-2 main protease (Mpro) inhibitor (also known as SARS-CoV2 3CL protease inhibitor)] —and co-packaged with ritonavir [a cytochrome P450) CYP) 3A inhibitor is a protease inhibitor to prolong nirmatrelvir]) EUA 105 (last FDA overwriting of EUA 105 of 2/1/2023: <https://www.fda.gov/media/155049/download> ; initial FDA EUA of 12/22/2021: <https://web.archive.org/web/20211222200348/https://www.fda.gov/media/155049/download> )
  - c. LAGEVRIO (molnupiravir [a ribonucleoside that is uptaken by viral RNA-dependent RNA-polymerases resulting viral mutations and viral mutagenesis]) EUA 108 (last FDA overwriting of EUA 108 of 2/1/2023: <https://www.fda.gov/media/155053/download> ; initial FDA EUA of 12/23/2021: <https://web.archive.org/web/20211223201214/https://www.fda.gov/media/155053/download> )
3. Steroids (like dexamethasone) in the suppression of the overactivation of the infected individual's immune system resulting in a cytokine cascade
4. There is no treatment for increasing bradykinin levels

While the **Means, Motives, and Intrinsic Opportunities** are consistent with the very nature and *modus operandi* of this **Viral Murderer, Coronavirus, SARS-CoV-2**, the:

- 1. Extrinsic Opportunities** of this **Viral Murderer** have been accentuated, promoted, and enhanced inadvertently by American Societal prejudices, indifference, ignorance, and misinformation; and
- 2. Extrinsic Impediments** of this **Viral Murderer** have been:
  - a. minimized, provisionally addressed in a disorganized and chaotic fashion, and overall hidden from public unawareness;
  - b. obfuscated, disregarded and dismissed by Medical Research, the Pharmaceutical industry, and Business magnified by their accentuation of their conflict-of-interests;
  - c. magnified by the attitude of: *The End Justifies the Means*;
  - d. exentuated by Personal Greed equated to professional and financial success;
  - e. and general witlessness and resultant lack of individual scrutiny and analysis promoted by:
    - i. overall American societal scientific illiteracy,
    - ii. publicly accepted disregard for history,
    - iii. dishonest and destructive overshadowing by political partisanism,
    - iv. and just plain selfishness and meanness.

**The story of the world-wide COVID-19 Pandemic in the United States of America is a national American epidemic tragedy imprinted forever in history and unfortunately, by the overall lack of early (<72 hours) uniform treatment response with exogenous immunoglobulins and antivirals, has become a commentary of man's stupidity and inhumanity towards his fellowman in this new millennium of the 21<sup>st</sup> Century.**

## Methods:

From April 2020 to the present (March 2023), the World literature--scientific, business parochial, and daily media—were perused, collected, recorded electronically, much were hard-copy filed--and over time three composite documents were submitted for preservation for history to the U.S. Copyright Office of the U.S. Library of Congress. From April 2020, analysis letters were composed and mailed to divisions of the U.S. Department of Health and Human Services (e.g.: FDA, NIAID , etc.), U.S. Department of Veterans Affairs (VA), and *The White House*.

**The first submission to the U.S. Copyright Office in June 2020 was addressed by the NIAID Communications Officer at the direction of Dr. Fauci establishing a case number: NIH NIAID #12276 and *The White House* press secretary acknowledge the COVID-19 convalescent plasma “issue” in the Friday afternoon press conference of June 19, 2020.**

...Finally, well second, to finally, we are encouraged that we continue to gather positive data on a number of therapeutics: heparin; dexamethasone or steroids as it's more commonly known; convalescent plasma; and Remdesivir have all shown promise in treating coronavirus. Preliminary findings in a large UK-based recovery trial found that when steroids were used there was a 30% reduction in death for coronavirus patients on ventilators. The FDA is reviewing this recovery trial data now. Additionally, on convalescent plasma there's more encouraging news in partnership with Mayo Clinic the Trump administration move very quickly on this therapy and it's earliest days recognizing that it showed promise. Through the FDA Mayo Clinic and the administration's work in our hand-in-hand partnership, we found that this treatment is very promising--this has shown that the administration has left no stone unturned in looking at every possible treatment at the very early stages. The lead investigator of this Mayo Clinic study, Dr. Michael Joyner, summed up his work in saying that convalescent plasma “continues to look promising” noting the “excellent news of this study which covered a diverse population of patients about 20% were African-American, nearly 35% Hispanic, 5% Asian, and 40% women. Prior experience with respiratory viruses and some data that have emerged globally suggest convalescent plasma has the potential to lessen the severity or shorten the length of the illness caused by COVID-19. The results from the Mayo underscore that promise. As you can see, the Trump administration and FDA led on identifying convalescent plasma as a therapeutic and the results are encouraging...

The establishment of NIH NIAID Case File# 12276 became crucial to the continued official accumulation of data for this report going forward as by U.S. Federal Law all must be preserved and is discoverable through a formal request submitted to the NIAID FIOA officer.

Confirmation of all documentation to the NIAID Director's Office (Anthony Fauci, M.D.) of ongoing continued preservation by the NIAID's Communications Officer's Office came in a form of a phone call over a year later on August 30, 2021, between Dr. Andrus and “Meg” on behalf of the office of Kara Harris, MPH, National Institute of Allergy and Infectious Diseases Communications and Liaison Officer, U.S. National Institutes of Health (NIH).

## Case Report of the Chronology of the Treatment of Presidents Trump and Biden:

In October 2020, [which was prior to any vaccine (*Active Immunization*)], the unvaccinated individuals of Rudy Giuliani, Chris Christy, Ben Carson, M.D., and President Donald Trump contracted COVID-19. Immediately, within 72 hours of diagnosis, all four were treated with a monoclonal antibody or cocktail and the antiviral remdesivir (a 5 day course) and all survived. <https://www.nytimes.com/2020/12/10/opinion/coronavirus-giuliani-regeneron.html>

Reportedly, President Trump received Regeneron's monoclonal antibody cocktail within ~4 hours of diagnosis (*Passive Immunization*), a multiple day course of the antiviral remdesivir (I.V. bid) was initiated within 18 hours, and dexamethasone was administered. In fact, after this treatment, President Trump bragged that he was cured! <https://www.forbes.com/sites/roberthart/2020/10/08/while-trump-touts-cure-made-by-regeneron-its-ceo-is-a-member-of-trump-golf-club/?sh=347f188860c8>

The Individual COVID-19 timelines of President Trump and President Biden were as follows:

### **President Trump:**

October 2020:	Contracted COVID-19 and was immediately treated with <i>Passive Immunization</i> (Regeneron's monoclonal antibody cocktail), a five-day course of the I.V. antiviral remdesivir, and also I.V. dexamethasone
January 2021:	First vaccine inoculation
March 1, 2021:	Second vaccine inoculation
Fall 2021:	Received a vaccine booster

### **President Biden:**

December 21, 2020:	First vaccine inoculation
January 11, 2021:	Second vaccine inoculation
September 27, 2021:	1 <sup>st</sup> vaccine booster
March 30, 2022:	2 <sup>nd</sup> vaccine booster
July 21, 2022:	Contracted COVID-19 and was treated with a five-day course of the oral antiviral Paxlovid
October 25, 2022:	3 <sup>rd</sup> vaccine booster (new version)



**Results:** Both President Trump and President Biden contracted the SARS-CoV-2 virus, clinically initiating COVID-19 symptoms, in which visa-à-vis one was unvaccinated while the other was vaccinated having contracted the virus later in the timeline. Both were appropriately treated as all individuals of the entire nation and the world should have been treated. The combination of (1) the administration of exogenous immunoglobulins or the body's utilizing endogenous immunoglobulins post-vaccination and (2) an antiviral are synergistic and should be given within the first 72 hours after diagnosis. This should have been and should be the Medical Standard of Care in the United States today for every man, woman, and child who contracts COVID-19 regardless of vaccination status or concomitant illnesses (e.g.: hypertension, diabetes, obesity, history of smoking, etc.)

In October 2020, the physicians caring for President Trump at Walter Reed Military Medical Center, FDA and NIH experts, medical publications, news commentators, the media, and the general public had the general impression that this combination was strictly experimental and thus not for the rank-and-file American. WHAT A BUNCH OF MEDICAL HOGWASH! This is the crux of the problem and the FDA, the NIH, the PHS, the CDC, Academic Medicine, all of United States Medicine, and all of the Federal Government were complicit in promoting this HOGWASH. As the case report of this summary exemplifies, AMERICAN MEDICINE failed the American people.

1.) This occurred because from March 13, 2020, to the present, the United States has been in an official Public Health Emergency (PHE). On that day, Secretary Azar suspended parts of EMTALA retroactive to March 1, 2020, thus officially abridging some part of every American's rights guaranteed by EMTALA:

- a. Stabilization
- b. Diagnosis
- c. Treatment / Appropriate Disposition

2.) The Biden administration has renewed the PHE and thus the EMTALA waivers on February 24, 2021 renewing them every 90 days until PL-118-3 was signed into law on April 10, 2023. In August of 2022, CMS stated that the waivers would terminate once the Public Health Emergency (PHE) was declared concluded. By the signing of PL-118-3 rescinding President Trump's Executive Order 9994 of March 13, 2020, the PHE is to be ended in the coming weeks. **The FDA and the NIH have a big ETHICAL and PRACTICAL problem since any drug or test, etc. designated as authorized (not FDA approved) under an EUA should by FDA (and NIH) policies and definitions revert to "Investigational" / "Experimental."**

3.) In 2018, The Right to Try Act became a Federal Law, PL-115-176, which stated that as soon as an experimental drug or biologic has completed a Phase I (Safety) Clinical Trial, any American could request off-protocol the experimental/investigational drug or biologic for their personal use in the treatment of their specific disease. Through the ambiguity of euphemisms (Authorized versus Approved), the FDA and the NIH have facilitated through the use of the *Emergency Use Authorization (EUA)* that no antiviral except VEKLURY remdesivir nor biologic except the mRNA Pfizer and Moderna vaccines became prescription drugs. All other Immunoglobulins and Antivirals to treat COVID-19 and the Vaccines to prevent and provide prophylaxis against COVID-19 retained their "Experimental status"

under the EUAs. In short, the FDA has not officially declared all other drugs in the treatment of COVID-19 “SAFE” through a completed Phase I study thus flagrantly avoided application of the Right to Try Act of 2018 (PL-115-176) by not officially declaring Phase I Clinical Trials “ever being completed.”

4.) While VEKLURY (remdesivir) is the only antiviral FDA approved in the treatment of COVID-19, the U.S. Government has promoted and provided through the Test and Treat Program under EUAs the oral Antivirals: Pfizer’s Paxlovid and Merck’s Lagevrio. Up until very recently, television advertisements for Pfizer’s Paxlovid which is authorized under an FDA EUA but not FDA approved as a prescription antiviral did not mention the very name of the antiviral, Paxlovid, and legally still should not as it is “Investigational” under an FDA EUA. **Thus, a non-FDA-approved oral antiviral, Paxlovid, is being marketed in deference to its competition with the intravenous antiviral VEKLURY (remdesivir), NDA 214787, which is a fully-FDA-Approved prescription drug.**

**Discussion:** During the initial year course of the disease of COVID-19 in the United States of America (USA) epidemic, early treatment (within 72 -120 hours of symptoms and diagnosis) with exogenous immunoglobulins (Passive Immunization—COVID-19 Convalescent Plasma) and the antiviral Remdesivir were *de facto* withheld from the vast majority of COVID-19 infected individuals in deference to the USA people waiting in anticipation for monoclonal antibodies, mRNA vaccines, and the oral antivirals which came a year or more later. The late-administration of treatment (>120 hours) or withholding completely of treatment with immunoglobulins and antivirals engendered by multiple divisions of the U.S. Department of Health and Human Services (e.g.: the FDA, the NIH, the NIH NIAID, PHS, etc.); the pharmaceutical and biologic industry, and *The White House* provided the opportunity to define the mortality of the natural course of untreated COVID-19 in a population by decades of life—very much akin to and analogous to the unethical Federal bureaucratic application of the Tuskegee Syphilis Project of the mid-twentieth century. The incidence of mortality attributable to COVID-19 in untreated or delayed treatment individuals by age-decade can be derived from the reports from the first year of the epidemic of the CDC which demonstrated a progressive age-related, mortality rate mathematically represented in Figures 1 & 2 and defined by two least-squared fits of:

0 – 45 years

Mortality rate (y) = 0.0004 (x) – 0.0023  $r^2 = 0.80$

46 – 90 years

Mortality rate (y) = 0.0067 (x) – 0.2647  $r^2 = 0.97$

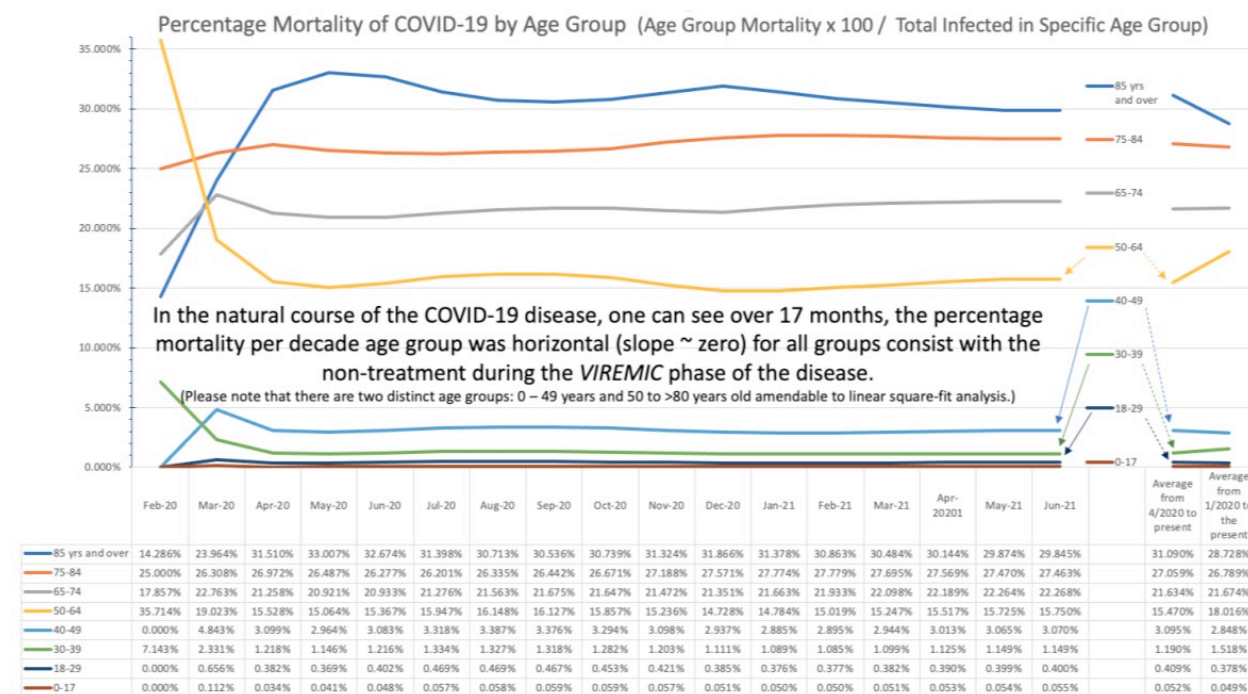


Figure 1: Y axis = monthly decade age group mortality due to COVID-19/total population of decade age group, Y axis = mortality rate in %. Data derived from the CDC database of sex and age mortality:  
[https://web.archive.org/web/20210217175653/https://www.cdc.gov/nchs/nvss/vsrr/covid\\_weekly/index.htm#SexAndAge](https://web.archive.org/web/20210217175653/https://www.cdc.gov/nchs/nvss/vsrr/covid_weekly/index.htm#SexAndAge)

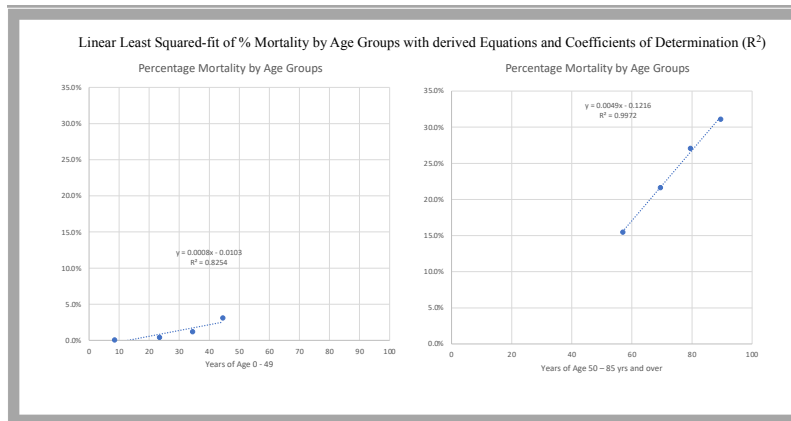


Figure 2 is derived from a calculated least-squared fit of the data from Figure 1. The slopes  $\times 100$  equals the fraction increasing (0-45 years): 0.04 mortality annual increase / years and (45-90 years): 0.67 mortality annual increase / years, respectively. Thus, adult mortality rate (45 years to 90 years) represents an increase of 0.67% mortality in each specific decade population per increasing year of life after 45 years of age.

Over the last 3 years, **two independent variables: TIME and AGE** stifled, inhibited, and promoted irrational rationing of the appropriate treatment applications in the vast majority of prospective Randomized Clinical Trials (RCT) COVID-19 treatment (not prophylaxis) studies as they were statistically underpowered (subject to Type II and Type III statistical errors); highly influenced by powerful research conflict-of-interest motivations; and misdirected and dismissed by egocentric financial and political incentives:

- (1) **TIME: American Medicine and Research ignored the appropriate timing of Early (less than 120 hours from diagnosis) treatment in the administration TO ALL of *exogenous immunoglobulins* and *antivirals* during the viremic phase of the disease.**  
[Instead, most studies were conducted during the later human-organism-response phases after the initial 72-120 hour viremic phase:

- a. Cytokine Cascade and
- b. Bradykinin Storm which is resultant from the entry of the Coronavirus, SARS-CoV-2 via the angiotensin converting enzyme 2 (ACE-2) receptor as-well-as the virus's ACE/ACE2 balance disruption and the activation of the Renin-Angiotensin-Aldosterone-System (RAAS) resulting in increases in bradykinin]; and

- (2) **AGE:** With the steep slope/increase in mortality rate with ages over 50 years (0.67% increased mortality/increasing age-year over 50 years of age), statistically very large comparative samples in all RCTs should have been employed to avoid a Type II error. A type II error is the assertion of a negative result from too-small-of-sample-sizes thus asserting equivalency of two comparison groups ( **$\beta$**  risk) when the two groups may actually be statistically different. Due to difficulty in recruitment in treatment RCT COVID-19 studies in which placebo controls were used, most, if not all, of the multitude RCTs enrolled in the U.S. National Library of Medicine *ClinicalTrials.gov* comparing treatment versus placebo were severely underpowered and the stated results were

**useless**. While the medically-statistical-accepted **alpha** ( $p=0.05$ , a 95% confidence level) regarding mortality were not met in most of these studies, an appropriate **beta (B)** (0.20) was never met in the RCTs and thus announcing negative results as definitive—as was consistently done--**were fallacious**. (e.g.: Argentine study, Prism study, etc.) While the Mayo Clinic / FDA COVID-19 **Expanded Access** (*FDA euphemism for Compassionate Use*) Protocol had a large number of COVID-19 Convalescent Plasma units (>94,000 patients treated) administered late **at the WRONG TIME (during the cytokine cascade and bradykinin storm) over the expanse of >50 - 90 years-of-age to 90 years)**, the 94,000 were not *de facto* eligible for any research as to the Protocol's **Compassionate Use status** as the World Health Organization and the U.S. Institute of Medicine previously had forewarned regarding Ebola.



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Type I and type II errors are the two classic pitfalls in statistical analysis: finding a difference when there is none (type I) and failure to find a true difference (type II). **There is, in addition, another important error that regularly appears in scientific journals. This error, the type III**

*error*,<sup>1</sup> occurs whenever the conclusions drawn are not supported by the data presented. In recent years, type III errors have been increasing in prevalence. Some illustrations drawn from recently published articles should serve to define my point. I have deliberately omitted citation of sources because my intent is to illustrate, not embarrass.

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President Joseph Biden  
President of the United States of America  
*The White House*  
1600 Pennsylvania Avenue  
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202-456-1414

**Re:** NIH NIAID Case #12276 USPS Priority mail: 9410 8036 9930 0153 7265 90  
0.1 2022-09-11 Dear Mr. President Case Report cover letter

Dear Mr. President:

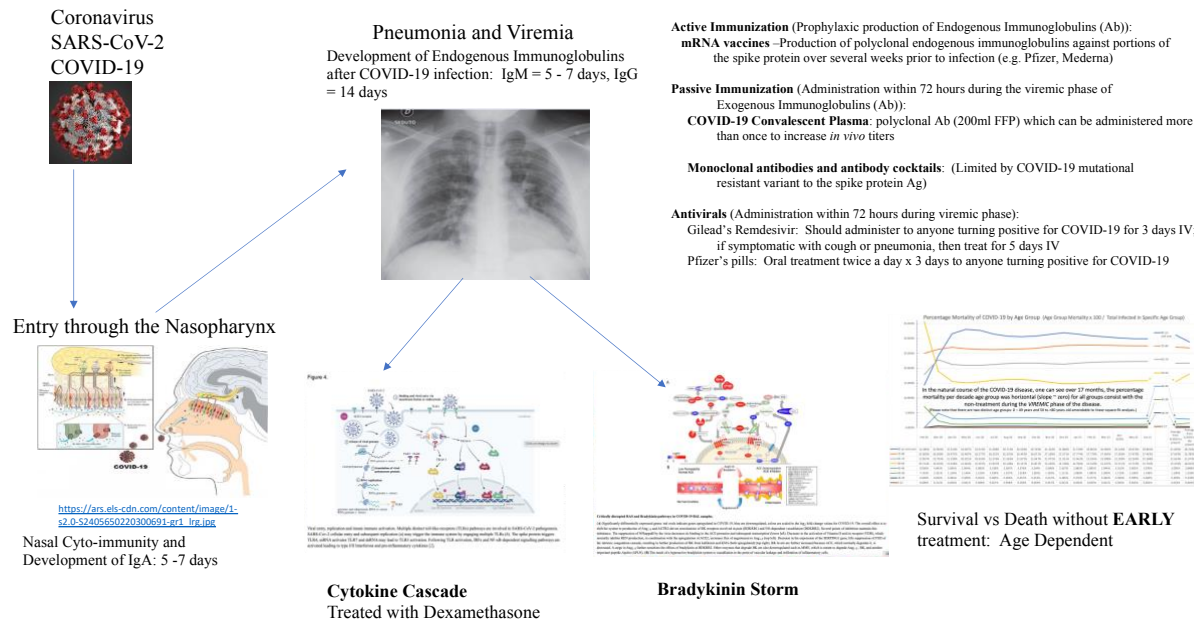
I apologize for the seemingly oppressive amount of material I present before you today. The case report that follows encapsulates our failings to individuals infected with coronavirus, SARS-CoV-2 (COVID-19) over the last 31 months.

### **Introduction:**

As a federal physician and surgeon, it is my duty to the American people and to yourself as our nation's leader to state frankly that American Medicine failed the American people in the **treatment** of those infected with COVID-19. For the last 120 years when dealing with a novel infectious disease of which our immune system is naïve, American Medicine has always had one immediately available **treatment** of convalescent plasma from individuals that have previously recovered from the disease. Over the last two years with our continuing ongoing lack of understanding of how crucial past history should direct us, American Medicine **failed to treat** COVID-19 appropriately in a standardize fashion: **EARLY** (<72 hours) in the contraction of the disease (Figure 1):

1. Collate and incorporate in our knowledge-base as many elements as possible regarding the *Pathophysiology* of the coronavirus, SARS-CoV-2
2. Distinguish the **treatment** options of an infected individual vs prevention and prophylaxis of non-infected individuals based on the *Pathophysiology* of the coronavirus, SARS-CoV-2, COVID-19
3. Distinguish (1) **Early Treatment** (within 72 hours of symptomatology and diagnosis) during the **VIREMIC PHASE** of the coronavirus, SARS-CoV-2 from (2) **Late Supportive Therapies** during the overwhelming **Systemic Response Phases** of the *Cytokine Cascade* and the *Bradykinin Storm*.

## Figure 1: Pathophysiology and Acute Treatment of COVID-19



## 1.002 2022-02-27 Pathophysiology and Acute Treatment of COVID-19

In dealing with any infectious disease one must (1) identify the source, (2) understand how it infects, (3) develop treatments for those that are infected, and (4) develop long-term methodologies of protection and prevention for those who are not infected. In March 2020, American Medicine jumped over any organized treatment strategy in the individual patient infected with COVID-19 emphasizing instead future approaches of long-term protection and prevention while ignoring early available treatment methodologies for the COVID-19 infected individual patient. The case study that follows epitomizes where we are today 31 months after the beginning of the American epidemic. I emphasize **epidemic** as opposed to **pandemic** because throughout the last two+ years, the FDA, the NIH, and all of American Medicine have not been precise or completely accurate in our definitions, in our thought processes, and in setting appropriate goals. As the President of the United States, you are above all else the ethical, moral leader of this country which was unfortunately contradicted previously by a narcissistic, self-absorbed, unscrupulous mindset akin to the 7th grade playground bully encouraging a reign of terror / fear among all who participate in the schoolyard.

### Case report:

A 66-year-old female patient last weekend who was visiting relatives in a contiguous state to her home developed a sore throat, headache, cough, coryza, and tested positive by a home nasal swab Ag-Ab test for COVID-19. She previously had received the two initial doses of the vaccine against COVID-19 and has had two boosters. The patient has a history of atrial fibrillation and is on Xarelto.

Knowing early administration of an antiviral or immunoglobulin (within 5 days of symptomatology) will modify/diminish the symptoms of COVID-19, this well-educated patient immediately called her personal physician's office to request a script for the oral antiviral Paxlovid. She was informed that her long-time doctor would not prescribe any medications if she was in another state even though she was in a contiguous state. She went on-line to locate a pharmacy through the COVID-19 Test-to-Treat program where she could receive Paxlovid and was rejected. She went to a local Hospital Emergency room in that contiguous state where she was told she must be tested again. The patient related that the nasal swabbing was superficial, hurried, and inappropriately administered—and the resultant report of the hospital ER was Ag-Ab screening was negative. The ER doctor stated that even if this test was positive (and the at-home test was absolutely positive and the patient was symptomatic), he would not give her a script for Paxlovid because he had never prescribed it before.

The patient went back on-line and found a proprietary teleconference physician service which deals with COVID-19. The patient paid the necessary fee (~\$140), and was assigned a physician who was two thousand miles away but who had a license in another contiguous state to the one she was at present within. Unlike all those previous healthcare personnel, this physician was not dismissive to the patient—he listened to the patient, reviewed her medication listing, and stated that Paxlovid was contraindicated as she was on Xarelto (rivaroxaban) placing her at a higher risk of hemorrhagic stroke with the combination of Paxlovid and Xarelto. He thus prescribed for her the present *Eli Lilly* monoclonal antibody bebtelovimab which is active against the omicron variant. The next day with the prescription in hand, the patient was infused with one intravenous dose of bebtelovimab in a small regional hospital of a second contiguous state. While the patient still had a significant sore throat and coryza 24 hours later, her overall systemic symptoms were minimal and 48 hours after the single infusion of bebtelovimab the patient felt much better. While the patient's severe cold-like symptoms of coryza, upper air way congestion, and cough are slowly improving, the patient had minimal systemic symptomatology, has no organ failure, and is alive.



## Results:

Immunotherapy and antivirals should be administered within 5 days of symptomatology and diagnosis which is consistent with the pathophysiology of disease COVID-19 caused by coronavirus, SARS-CoV-2. (Appendix I)

The COVID-19 virion is an 80 – 120 nm RNA coronavirus which is mainly transmitted by a respiratory route. **Mr. President**, there is no such thing as an antiviral mask. N95 masks mean that 95% (a 0.95 confidence level) of particles below 300 nm will be obstructed affording a high-level (but not absolute) protection for the non-infected individual. For the infected individual in this case report, it is more important for this individual where a mask. As the moist phlegm particles in an infected individual from a sneeze or a cough are usually larger than 300 nm, masks are the best protection (not for the wearer) but for those being sneezed upon or coughed on by infected individuals. Thus, while wearing a mask provides the wearer theoretically ~95% obstructive protection from the coronavirus, SARS-CoV-2, that may be on the outside of such a mask, it is the embodiment of the Golden Rule for those infected with COVID-19 with regards to limiting exposure to the non-infected of humanity around them: *Do unto others as you would wish would do unto you.*

I. Ever since U.S. DHHS Secretary Azar on March 13, 2020, waived under his 1135 waiver authority of the Social Security Act retroactive to March 1, 2020, some aspects of the Emergency Medical Treatment and Labor Act (EMTALA). As few in the U.S.A. knew what this even meant, the guaranteed rights of every American under EMTALA of the COBRA of 1986 have been *de facto* abridged and suspended for the last 31 months to this very day. <https://www.cms.gov/files/document/covid-19-emergency-declaration-waivers.pdf> EMTALA (the Emergency Medical Treatment and Labor) Act of COBRA, Consolidated Omnibus Budget Act of 1986, PL-99-272) is the guarantee to all Americans when they present to hospital ERs of the following:

1. Resuscitation and stabilization,
2. Diagnosis and treatment, and
3. Disposition

If the Emergency Room physician had done what he did in a time when rights under EMTALA were intact and not waived initially by the Trump Administration (and continuing to this day by the Biden Administration), the physician and his hospital would each have faced \$50,000 fines adjudicated and levied by the U.S. Department of Health and Human Services (DHHS) on behalf of the patient. (**Mr. President**, please understand that the \$50,000 fines levied against the physician and the hospital are **NOT** covered by any malpractice carrier.) While the Trump Administration initiated the waivers, the Biden Administration renewed the waivers in February 2021 and, as of August 18, 2022, CMS (Centers for Medicare and Medicaid Services) has sustained the waivers from EMTALA by stating that only when the COVID-19 Public Health Emergency (PHE) is officially concluded that the waivers involving **the abridgement of** individual American's rights under EMTALA will be terminated. (**Mr. President**, you have an obligation to the American people to conclude the present Public Health Emergency (**PHE**) -- *possibly by an Executive Order?!)*

The Emergency Room physician epitomizes the confusion across the nation over the appropriate algorithm in the **EARLY treatment (within less than 72 hours of diagnosis)** of those infected with COVID-19. (Appendix I) Appendix II is a rough chronology of the mistakes from March 2, 2020 forward to the present, that both Administrations have been parties to.

II. While Dr. Adams had good intentions, on March 19, 2020, Jerome Adams, M.D., U.S. Surgeon General, published on the Internet a Public Service Announcement (PSA) that muddled the waters even more by stating that Americans who thought they were infected with COVID-19 should not go to a hospital emergency room which is somewhat pervasive mind-set even today.

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<https://www.facebook.com/WhiteHouse/videos/psa-if-you-are-sick/196091611816606/>

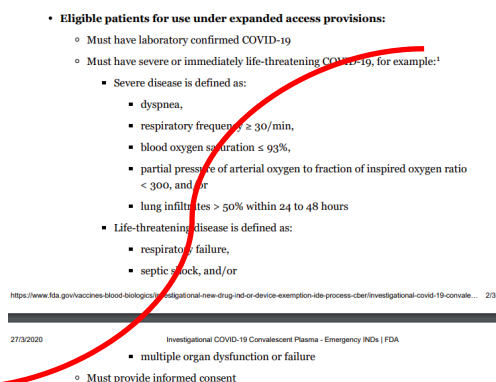
As the Nation's doctor, I often get asked: What should I do if I think I might have coronavirus? Well, it is important to know the symptoms--they include: fever, cough, and shortness of breath. If you are having these symptoms or worry you might have coronavirus, please call your healthcare provider. **We don't want you to go into the ER or the doctor's office without talking to them first because you might spread coronavirus to someone else.** They will help you think through and learn how to react including figuring out where to go to get tested if necessary.

Dr. Jerome Adams, PSA, If You Are Sick, March 19, 2020.

III. On March 24, 2020, instead of recommending **EARLY ADMINISTRATION in the disease** (during the *viremic phase* ~72 – 96 hours after diagnosis) with COVID-19 Convalescent Plasma and the antiviral Remdesivir, the FDA recommended a **WRONG TREATMENT TIME** of the **LATE ADMINISTRATION in the disease** (during the *cytokine cascade* and *bradykinin storm* phases > ~72 hours after diagnosis). To this day, *de facto* **rationing**, is still present in the mindset of the majority of healthcare providers, the federal government, and the American people. Figure 2:

### 1) 2020-03-24 U.S. Food and Drug Administration: Investigational COVID-19 Convalescent Plasma – Emergency INDs, March 24, 2020.

[https://notifylibrary.org/sites/default/files/Investigational%20COVID-19%20Convalescent%20Plasma%20-%20Emergency%20INDs%20\\_%20FDA.pdf](https://notifylibrary.org/sites/default/files/Investigational%20COVID-19%20Convalescent%20Plasma%20-%20Emergency%20INDs%20_%20FDA.pdf)



<sup>1</sup>Wu Z, McGoogan JM. Characteristics of and Important Lessons From the Coronavirus Disease 2019 (COVID-19) Outbreak in China: Summary of a Report of 72 314 Cases From the Chinese Center for Disease Control and Prevention. JAMA. Published online February 24, 2020. doi:10.1001/jama.2020.2648

## Discussion:

**Mr. President**, while the physicians and administrators of the agencies (e.g.: FDA, CDC, NIH, BARDA, PHS, etc.) of the U.S. Department of Health and Human Services (DHHS) and the U.S. Department of Veterans Affairs will argue to discredit my submission to you, **Mr. President**, this Case Report is an anecdotal tale that **epitomizes** that which is occurring throughout the nation to COVID-19-infected individuals today:

- (1) While the Ag-Ab screening tests are reportedly ~82% - ~89% statistically sensitive, **the calculation of “Sensitivity” — True Positive / (True Positive + False Negative)** provides a **“POSITIVE”** for an Ag-Ab test which is statistically a **“POSITIVE”** for a medical screening test purposes and a repeat Ag-Ab screening test **DOES NOT NEGATE the first result.**

[https://www.nottingham.ac.uk/nmp/sonet/rlos/ebp/sensitivity\\_specificity/page\\_four.html#:~:text=Sensitivity%20\(the%20proportion%20of%20patients,true%20positive%20plus%20false%20negative.&text=Specificity%20\(the%20proportion%20of%20patients,true%20negative%20plus%20false%20positive.](https://www.nottingham.ac.uk/nmp/sonet/rlos/ebp/sensitivity_specificity/page_four.html#:~:text=Sensitivity%20(the%20proportion%20of%20patients,true%20positive%20plus%20false%20negative.&text=Specificity%20(the%20proportion%20of%20patients,true%20negative%20plus%20false%20positive.)

**Mr. President**, there is no such thing as a “Best two out of three, or three out of five, ....” with regards to the Medical Statistical Term: Sensitivity. Repeating the same medical “screening test” and choosing a possible false negative result as statistically better over a positive is an incorrect interpretation. That is why the accepted practice for medically statistics to reject the null hypothesis ( $H_0$ ) (a true difference between to test groups) is a 0.95 confidence level which is roughly two Standard Deviations (SD) from the mean (actually,  $Z=1.96$  at a  $CI=0.95$ ).

[https://www.westga.edu/academics/research/vrc/assets/docs/confidence\\_intervals\\_notes.pdf](https://www.westga.edu/academics/research/vrc/assets/docs/confidence_intervals_notes.pdf)

None of the Ag-Ab “COVID-19 screening tests” meet that standard.

**Mr. President**, as Dr. Fauci and Dr. Collins are still U.S. Government employees, you might request their presence in *The Oval Office* to discuss with you an explanation as to why today in our national response to COVID-19 some Medical Tests (and Treatments) are accepted and others are rejected. The business community has used this ambiguity in their definitions and their applications of “products” to advantageously market products (and discredit the competition) throughout our society for years. Before your meeting with Drs. Fauci and Collins, you might wish to review Darrell Huff’s Best Seller of the 1950s entitled: *How to Lie with Statistics* which can be accessed *in toto* in the Website below: [https://online225.psych.wisc.edu/wp-content/uploads/225-Master/225-UnitPages/Unit-07/Huff\\_StatisticsBook\\_1954.pdf](https://online225.psych.wisc.edu/wp-content/uploads/225-Master/225-UnitPages/Unit-07/Huff_StatisticsBook_1954.pdf) A few unrelated examples from our time:

"four out of five dentists surveyed recommend sugarless gum for their patients who chew gum". <https://knowyourmeme.com/memes/9-out-of-10-dentists> 0.80

According to the little cartoon box for Cologuard television ads: “I’m convenient and find 92% of colon cancers...even in early stages. I’m for people 45 plus at average risk for colon cancer, not high risk.

<https://www.youtube.com/watch?v=JsC3rmtzXP0>

[http://www.tarrantidocitors.com/blog-cologuard.html#:~:text=Cologuard's%20accuracy%20rate%20for%20detecting\\_14%25%20false%2Dpositive%20rate](http://www.tarrantidocitors.com/blog-cologuard.html#:~:text=Cologuard's%20accuracy%20rate%20for%20detecting_14%25%20false%2Dpositive%20rate)

### COVID-19 PCR versus antigen test sensitivity “screening tests”:

[https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2791915#:~:text=Antigen%20test%20sensitivity%20was%2050,CI%2C%2069%25%2D83%25:](https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2791915#:~:text=Antigen%20test%20sensitivity%20was%2050,CI%2C%2069%25%2D83%25;)

Antigen test sensitivity was 50% (95% CI, 45%-55%) during the infectious period, **64% (95% CI, 56%-70%)** compared with same-day RT-PCR, and 84% (95% CI, 75%-90%) compared with same-day cultures. Antigen test sensitivity peaked 4 days after illness onset at 77% (95% CI, 69%-83%).

November 5, 2021: Pfizer’s novel COVID-19 oral antiviral treatment candidate reduced risk of hospitalization or death by 89% in Interim Analysis of Phase 2/3 EPIC-HR study. <https://www.pfizer.com/news/press-release/press-release-detail/pfizers-novel-covid-19-oral-antiviral-treatment-candidate>

Pregnancy tests which have a whole range of sensitivities when the common misinterpretation is that the test answer should be binary: Yes or No:  
<http://getthediagnosis.org/diagnosis/Pregnancy.htm>

- (2) The patient with COVID-19 symptomatology of this **Case Report** presented within 5 days of COVID-19 positivity of the screening test which diagnosed COVID-19, and was rejected by her private doctor’s office, the ER doctor, and the **Test and Treat** website.
- (3) Only when the individual newly-infected with COVID-19 finds a healthcare professional who is well-read and analytically discerning do patient

Unlike Mrs. Biden and yourself when you immediately were initiated on Paxlovid, the individual patient in the community has to jump through many hoops due to physician, nurse practitioner, and public **ignorance, misinformation, and commercial upselling**. The U.S. Department of Health and Human Services agencies, e.g.: FDA, NIH, CDC, PHS, BARDA, etc; U.S. Department of Veterans Affairs through the Veterans Health Administration; and all of American Medicine (e.g.: private and public practice; the Universities and Teaching Hospitals; Medical Publications like *The New England Journal of Medicine*, etc.) have **literally abandoned the individual American patient** when it comes to an organized treatment protocol universal for all those newly COVID-19 infected Americans. This is tantamount to *The Tuskegee Syphilis Experiment (TSE)* of the four middle decades of the twentieth century. When President Bill Clinton, who apologized for the U.S. Government a quarter-of-a-century later after the TSE had become public in 1972, there were only a few African-American sharecroppers of the study that were still alive.

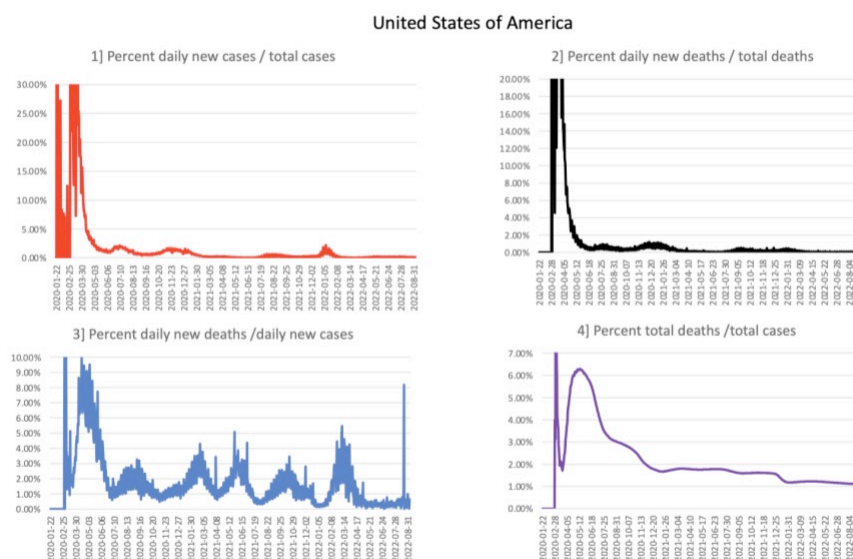
So, **Mr. President**, when in the U.S.A., are we going to apologize to the families of the 1,000,000+ dead Americans from COVID-19 and those who survived compromised by organ failure, etc. in which **EARLY administration of immunoglobulins and antivirals were NOT offered or administered** within 5 days of identification of the disease in the individual even when the individual requested them (refusal to give a drug or biologic is a violation of the intent of Right to Try Act of 2018, PL-115-176? The FDA and NIH have perpetuated this by not declaring any “Phase I Clinical Trials *Completed*” even though ***in practice* the FDA has deemed these drugs and biologics de facto safe** as the U.S. Government purchased million of units of vaccines, monoclonal antibodies, and antivirals for distribution?

Mr. President, more than anything else for the people of the United States, you need to bring the COVID-19 epidemic officially “to closure” the Public Health Emergency (PHE) by rescinding the COVID-19 National Emergency Declaration of March 13, 2020.—which will promote the legal termination of the EMTALA waivers as promised by the U.S. Department of Health and Human Services in August of this year.

The FDA, the NIH, and the VA have all been party to disinformation, which *de facto* obstructed the delivery of EARLY TREATMENT (not prevention) in the course of the COVID-19-infected individual’s disease (< 72 hours from time of diagnosis). Unfortunately, disinformation, self-promotion, and withholding of treatments in the first few months (3/2020–11/2020) of the U.S. COVID-19 Epidemic, have pervasively advanced **that which Elisabeth Kubler-Ross described in her landmark publication *On Death and Dying*: Denial and Isolation, Anger, Bargaining, and Depression.** Only if the present animosity, intolerance, and hatred of your fellow man throughout the United States is discontinued, will we as a nation survive and be able to go forth successfully. We need to profess in our daily lives that which is on the inner north wall of the Lincoln Memorial:

With malice toward none; with charity for all; with firmness in the right, as God gives us to see the right, let us strive on to finish the work we are in; to bind up the nation’s wounds; to care for him who shall have borne the battle, and for his widow, and his orphan—to do all which may achieve and cherish a just, and a lasting peace, among ourselves, and with all nations.

**Mr. President**, we as a country need to forgive ourselves. Over the course of the last 30 years, *we have become an extremely self-centered, financially-driven, intolerant society of the individual towards the individual with a differing viewpoint from ourselves.* This has been magnified in our 31 month confrontation with the coronavirus, SARS-CoV-2, COVID-19 having become a seemingly insurmountable enemy. As with all novel infectious diseases in which humanity is initially immunologically naïve, the American epidemic began with a series of epidemic peaks **that went untreated in any EARLY organized fashion:** not with immunoglobulins nor antivirals. (Figure 3):



While there will be recurrent peaks in the future, over the course of time, the incidence of COVID-19 will taper asymptotically as it becomes an ENDEMIC disease throughout our nation and the world. As the endemic development of any disease require centuries to diminish, the transition to resolve as an Endemic Virus if **untreated** in the EARLY course of the infection (< 72 hours from diagnosis) in every individual, will be prolonged.

From March 2, 2020, to the present, we have officially **NOT TREATED in any EARLY organized fashion COVID-19** with immunoglobulins nor antivirals. My submissions to date have been to point out that we have not uniformly treated those infected with the COVID-19 disease in any organized fashion.:

**Active immunization** (vaccines) does not treat the disease in an infected individual—but, rather, stimulates the endogenous formation of B-cells (plasma cells) thus leading to the systemic IgM and IgG production in vaccinated individuals for prevention and prophylaxis.

**Passive immunization** (polyclonal exogenous antibodies—COVID-19 Convalescent Plasma—and monoclonal antibodies and monoclonal cocktails) and **antivirals** administered if given **EARLY** (within <72 hours diagnosis) are effective in the **treating** of the disease. This last month when Mrs. Biden and yourself were treated with Paxlovid, the antiviral was used to suppress the active virus in your nasopharynx. While you both were previously stimulated systemically by an mRNA vaccine for your B-cells to produce monoclonal (or limited polyclonal) IgM and IgG systemically, your upper airways were naïve with regards to IgA production and thus unprotected when coronavirus, SARS-CoV-2 was detected on a nasal swab. In the future, anticipated nasal COVID-19 vaccines may address the lack of IgA in the nares (the endogenous immunoglobulin in the nasal and upper airway mucosa) in individuals previously vaccinated and boosted with systemic vaccine antigens.

For the systemically unvaccinated (individuals who are completely naïve to coronavirus, SARS-CoV-2, COVID-19 have not developed systemic endogenous IgM and IgG), the severity of COVID-19 illness and mortality is greatest. As no organized effort in 2020 in the United States was initiated to treat **EARLY (within < 72 hours of diagnosis)** with immunoglobulins and antivirals, the mortality rates by age were static for months (See figure 3) and defined mathematically by:

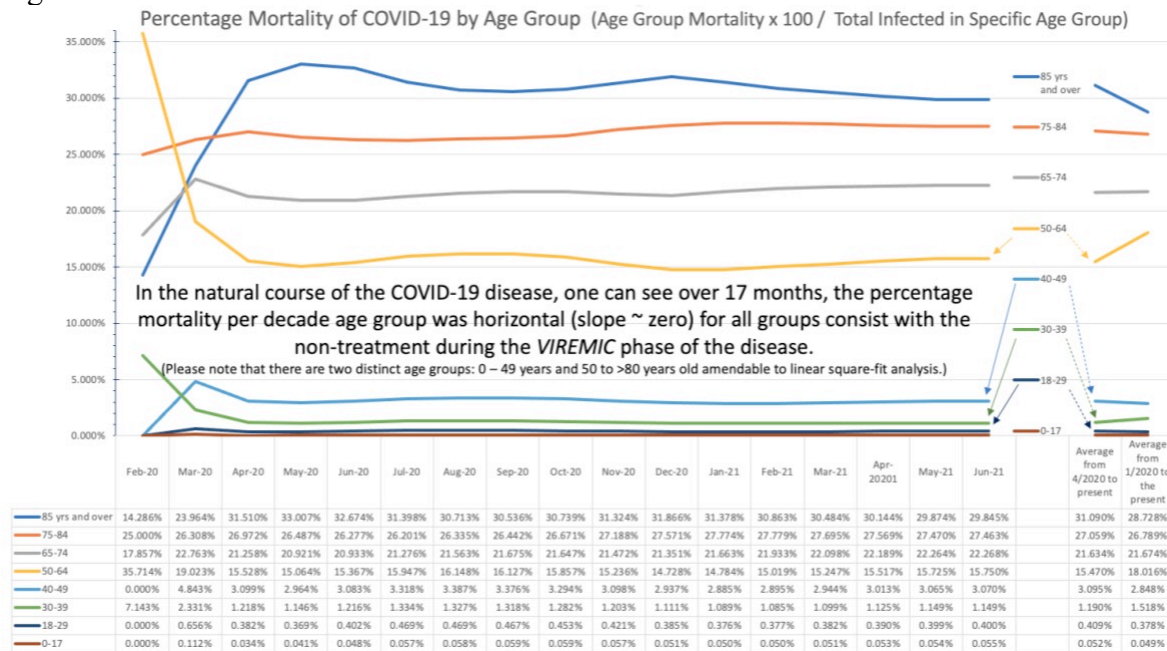
**Figure 3: Mortality linearly related in unvaccinated individuals**

(x = age year; y = calculated mortality rate prevalence by age-year):

- |                             |                        |               |
|-----------------------------|------------------------|---------------|
| i. 0 – 45 years of age:     | $y = 0.0008x - 0.0103$ | $R^2 = 0.825$ |
| ii. 46 to >85 years of age: | $y = 0.0049x - 0.1216$ | $R^2 = 0.997$ |



Figure 4



In October 2020, the privileged unvaccinated individuals of Rudy Giuliani, Chris Christy, Ben Carson, M.D., and President Donald Trump contracted COVID-19. Immediately within **72 hours of diagnosis**, all four were treated with a monoclonal antibody or cocktail and the antiviral Remdesivir (a 5 day course) and all survived. Reportedly, President Trump received Regeneron's monoclonal antibody cocktail within ~4 hours of diagnosis and a multiple day course of Remdesivir (I.V. bid) was initiated within 18 hours. In fact, after this treatment, President Trump bragged that he was cured! <https://www.forbes.com/sites/roberthart/2020/10/08/while-trump-touts-cure-made-by-regeneron-its-ceo-is-a-member-of-trump-golf-club/?sh=6247615360c8>

The combination of the administration of exogenous immunoglobulins and an antiviral are synergistic and should be **given within the first 72 hours after diagnosis and should be the Medical Standard of Care in the United States today for every man, woman, and child who contracts COVID-19** regardless of vaccination status or concomitant illnesses (e.g.: hypertension, diabetes, obesity, history of smoking, etc.)

In October 2020, the physicians caring for President Trump at Walter Reed Military Medical Center, FDA and NIH experts, medical publications, news commentators, the media, and the general public had the general impression that this combination was strictly experimental and thus not for the rank-and-file American. **WHAT A BUNCH OF HOGWASH! Mr. President,** this is the crux of the problem and the FDA, the NIH, the PHS, the CDC, Academic Medicine, all of United States Medicine, and all of the Federal Government were complicit in this **HOGWASH.** As the case report of this summary exemplifies, **AMERICAN MEDICINE failed the American people.**

Mr. President:

- 1.) This occurred because from March 13, 2020, to the present, the United States has been in an official Public Health Emergency (PHE). On that day, Secretary Azar suspended parts of EMTALA retroactive to March 1, 2020, thus officially abridging some of every American's rights guaranteed by EMTALA:
  - a. Stabilization
  - b. Diagnosis
  - c. Treatment / Appropriate Disposition
- 2.) Your administration has continued the waivers in February 2021; and, in August of 2022, it stated that the waivers would terminate once the Public Health Emergency (PHE) was declared concluded. **BUT, at present, there is no end in sight as the PHE has not been officially concluded by you.**
- 3.) In 2018, The Right to Try Act of 2018 became a Federal Law, PL-115-176 which stated that as soon as an experimental drug or biologic had completed a Phase I (Safety) Clinical Trial, any American could request *off protocol* the experimental drug or biologic for the specific disease. The NIH and the FDA have facilitated that no drug (except Remdesivir) or biologic (the original Pfizer vaccine) as they are prescription drugs can be requested because all other Immunoglobulins and Antivirals to treat COVID-19 and the Vaccines to prevent and provide prophylaxis against COVID-19 retain their "Experimental status" under the EUAs. In short, the FDA has not officially declared all other drugs in the treatment of COVID-19 "SAFE" thus flagrantly avoiding application of the Right to Try act of 2018 (PL-115-176) by not officially declaring the Phase I Clinical Trials "ever being completed." **Mr. President, how can the U.S. Government provide Oral Antivirals: Pfizer's Paxlovid and Merck's Lagevrio through the Test and Treat Initiative <https://aspr.hhs.gov/TestToTreat/Pages/default.aspx> under EUA's if the FDA has not yet declared them SAFE by the completion of Phase I clinical trials? <https://www.cdc.gov/mmwr/volumes/71/wr/mm7125e1.htm> . Mr. President, should you not request an opinion of Attorney General Garland regarding this conundrum?**
- 4.) Why would the NIH and FDA continue such misinformation? Randomized Controlled Trials (RCTs) usually compare the drug or biologic to a Placebo Control Group even though that may be Unethical. Placebo Groups during an epidemic especially with a disease of highly variable age-correlated mortality and NIH, VA, and BARDA funding, were threatened with elimination by The Right to Try Act of 2018, (PL-115-176). **All federal agencies that have circumvented *The Right to Try Act of 2018, (PL-115-176)* have done an extreme disservice to the American people.**
- 5.) Changing, misdirecting, or destroying URLs in Federal Government websites has been pervasive in the handling of U.S. Documentation over the last twenty-five years, at least. *Electronic overwriting* of Federal documents without noting what has been overwritten is today *status quo*. In short, these practices allow for Destruction of Federal Government policies, documents, memos, handbooks, etc. -- **THIS IS ILLEGAL and it is daily**

**practice in all the U.S. Departments and Agencies of the Executive Branch of the Federal Government** of which you, Mr. President, are Constitutionally “The Boss.”

**Mr. President, I initiated this cover letter and reiterate that:** As a federal physician and surgeon, it is my duty to the American people and to yourself as our nation’s leader to state frankly that American Medicine failed the American people in the **treatment** of those infected with COVID-19.” It is my hope that you will take all of this under your advisement. Please note that much of my submission has previously been sent to the U.S. Copyright Office for preservation for history and the total submission today is for *educational purposes only*. I waive any personal financial rights to the material in this submission. Thus, the U.S. Government can do what they will with this submission.

I will also forward copies of this material to:

1. The Office of VA General Counsel as they are the: “Designated Agency Ethics Official (DAEO) as they are the “safe harbor” regarding any submission of a VA employee to the Federal Government;
2. DVA Secretary McDonough, U.S. Department of Veterans Affairs;
3. Anthony S. Fauci, M.D., Director of the NIAID;
4. Kara Harris, MPH, Section Chief for Controlled Correspondence and Public Inquires, Legislative Affairs and Correspondence Management, U.S. National Institutes of Health, and U.S. Department of Health & Human Services who when given my correspondence of June 2020 by Dr. Fauci responded by establishing: **NIH NIAID Case #12276** which under the Freedom of Information Act is discoverable if requested by every American guaranteed by the 1<sup>st</sup> Amendment to the U.S. Constitution.
5. Abigail Carlson, M.D., formerly in the Division of Infectious Diseases, St. Louis VAMC, who I worked with as a colleague and a friend. Dr. Carlson now is in the Infectious Diseases of the CDC and can validate my sincerity and truthfulness in this submission to Dr. Walensky, Director of the CDC.

**Mr. President, thank you for taking this information under consideration.**

Respectfully,

Charles H. Andrus, M.D., F.A.C.S.  
Physician and Surgeon, Surgical Services (112-jc), St. Louis VAMC,  
Veterans Health Administration, U.S. Department of Veterans Affairs

Cc:

Catherine Mitrano, J.D., and Michael R. Hogan, J.D.  
Office of General Counsel (26)  
Designated Agency Ethics Official (DAEO)  
810 Vermont Ave, N.W.  
Washington, D.C. 20420  
Phone: 202-360-2598

**Re: NIH NIAID Case #12276**

USPS Priority mail: 9410 8036 9930 0153 7266 06

Anthony S. Fauci, M.D.  
Director of the U.S. National Institute of Allergy and Infectious Diseases  
U.S. National Institutes of Health  
U.S. Department of Health & Human Services  
5601 Fishers Lane, MSC. 9806  
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Phone: 301-496-5717 (last varified July 2020)

FAX: 301-402-3573 (last varified July 2020)

**Re: NIH NIAID Case #12276**

USPS Priority mail: 9410 8036 9930 0153 7266 13

The Honorable Denis McDonough  
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**Re: NIH NIAID Case #12276**

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Abigail Carlson, M.D.  
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**Re: NIH NIAID Case #12276**

USPS Priority mail: 9410 8036 9930 0153 7286 17

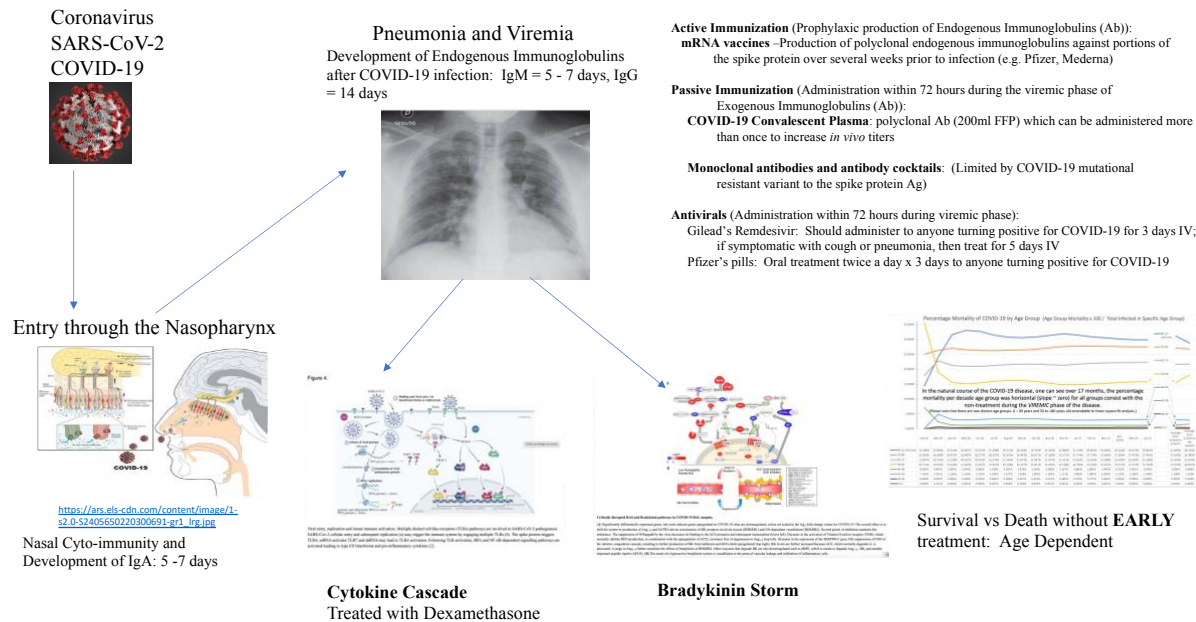
Kara Harris, MPH  
Section Chief for Controlled Correspondence and Public Inquires  
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Phone: 240-627-3693

**Re: NIH NIAID Case #12276**

USPS Priority mail: 9410 8036 9930 0153 7286 24

## Appendix I: Pathophysiology, Clinical Identification, Treatment, Support, and Prevention



### 1.002 2022-02-27 Pathophysiology and Acute Treatment of COVID-19

#### 2. Pathophysiology of the Coronavirus SARS-CoV-2 (COVID-19)

- Size 80 -120 nm
- Type: RNA coronavirus
- Transmission: mainly respiratory (through the nares and oral inhalation) and possibly by contact of contaminated secretions
- Entry through upper airway and through the attachment to the pneumonocytes of the lungs via the ACE2 receptors of the renin-angiotension-system (RAS)
- Clinical expression:
  - Early (72 – 120 hours)—The Viremic Phase: Bilateral pneumonia, headaches, cough, malaise, diminished olfactory sensitivity etc.
  - Late (> ~120 hours) – host immunologic response, multisystem involvement including respiratory deterioration, etc.
    - Cytokine cascade
    - Bradykinin storm
- Outcome: Mortality linearly related in unvaccinated individuals  
(x = age year; y = calculated mortality rate prevalence by age-year):

- 0 – 45 years of age:  $y = 0.0008x - 0.0103$   $R^2 = 0.825$
- 46 to >85 years of age:  $y = 0.0049x - 0.1216$   $R^2 = 0.997$

#### 3. Clinical Identification:

- Polymerase Chain Reaction (PCR) <https://www.ncbi.nlm.nih.gov/probe/docs/techpcr/> and <https://pubmed.ncbi.nlm.nih.gov/21400274/>
- Enzyme Linked Immunosorbent Assay <https://www.ncbi.nlm.nih.gov/books/NBK555922/>

4. Isolation, quarantine, masks, etc. (Please note, Mr. President, there is no such thing as an antiviral mask. N95 masks prevent passage of 95% (a 0.95 confidence level—2 standard deviations from the mean) of particles < 300 nm—thus 5% of COVID-19 particles (80 – 120 nm) can potentially get through by Brownian movement. This is somewhat analogous to a sparrow lighting in a cyclone fence and then flying through. All masks with regards to COVID-19 particles really more-protective to the individuals who come in contact with COVID-19 nares-positive individuals who are wearing masks. In this COVID-19 epidemic, the utilization of Masks epitomized one of the most noble of human attributes to which we aspire: *Do unto others as you would wish them to do unto you.*)

5. Therapies:

- a. Immunotherapies (Passive Immunization—Exogenous Antibodies)  
(optimum administration within 72-120 hours from diagnosis):
  - i. Polyclonal antibodies: COVID-19 Convalescent Plasma and Sera (These could be available as units or ½ units of convalescent fresh frozen plasma through every blood bank collection service throughout America including the non-for-profit American Red Cross and propriety blood banks like ImpactLife.
  - ii. Monoclonal antibodies and antibody cocktails.  
(Discussion of development of COVID-19 resistance by Molecular Darwinism):
    1. Eli Lilly's Bamlanivimab plus Etesevimab
    2. Regeneron's Casirivimab plus Imdevimab
    3. GlaxoSmithKline's Sotrovimab
    4. Eli Lilly's Bebtelovimab
- b. Anti-viral agents. (optimum administration within 72-120 hours from diagnosis)
  - i. IV agents, e.g.: Gilead's VEKLURY: Remdesivir, NDA#214787
  - ii. Oral agents, e.g.: Pfizer's Paxlovid and Merck Sharp & Dome's LAGEVRIO: molnupiravir
- c. Steroids -- Dexamethasone
- d. Other

6. Prevention:

- a. Vaccines (Active Immunization—Endogenous Antibodies)
  - i. mRNA vaccines: endogenous development of IgM and IgG
  - ii. Nasal vaccines: development of IgA
- b. Treatment with Passive Immunization – Exogenous Antibodies
  - i. Exposed patients – immediate dosing
  - ii. Immunosuppressed patients when weak or no response to mRNA vaccines - repeated dosing every 8 weeks of Passive Immunization with repeat dosing intervals dosing with antivirals



- iii. Monoclonal gammopathies (monoclonal plasma cell tumors) – e.g.:  
multiple myeloma as General Colin Powell had – repeated dosing every 8  
weeks of Passive Immunization with repeat dosing interval with antivirals
  - iv. Prophylaxis with Passive Immunization in patients with other high risk  
situations as a bridge until Active Immunization has been acquired
7. Supportive Care:
- a. O<sub>2</sub>: Nasal prongs – masks – ventilators
  - b. Supportive medications: pressors, etc.
8. Outcomes:
- a. Epidemiology:
    - i. Pandemic v Epidemic v Endemic
    - ii. Herd Immunity, what is it?
      - 1. By host disease acquisition
      - 2. By active immunization
      - 3. By passive immunization
  - b. Chronic Outcomes
    - i. Resolution without residuals
    - ii. Long-term COVID-19
    - iii. Chronic morbidities
    - iv. resultant organ failures
    - v. Deaths

## Appendix II: An abbreviated timeline of Immunoglobulin and Antiviral Therapy:

- I. In *The White House* on March 2, 2020, with several physicians present including Dr. Birx, Dr. Fauci, Dr. Hahn, Dr. Schleifer, etc., the President and Vice-President of the United States were introduced to the CEOs and Medical Directors of Pharmaceutical Drug and Biologics companies regarding anticipated future production of vaccines, monoclonal antibodies, and antivirals (Table 1). <https://www.c-span.org/video/?469926-1/president-trump-meeting-pharmaceutical-executives-coronavirus> Representatives of the Association of American Blood Banks (AABB) and the American Red Cross were not present. Unfortunately, Leonard Schleifer, M.D., PhD, CEO and Co-founder of Regeneron pharmaceuticals, *explained monoclonal antibodies with a misnomer: **Passive Vaccination** which preclude the distinction between **Active Immunization** (vaccination to develop endogenous immunity—systemic IgM and IgG) and **Passive Immunization** (Immunoglobulins that are given as exogenous immunoglobulins—IgG: COVID-19 Convalescent Plasma [polyclonal antibodies] which were available and could be produced in mass quantities by the American Blood Banks as fresh frozen convalescent plasma (FFCP) and monoclonal antibodies and cocktails which were unavailable in March 2020.* [https://www.youtube.com/watch?v=31i6p\\_stzW8](https://www.youtube.com/watch?v=31i6p_stzW8) All the physicians in the room on that day **failed the American people** for NOT correcting Dr. Schleifer's misnomer of **Passive Immunization** as "Passive Vaccination." In strict medical terminology, Passive Vaccination DOES NOT EXIST. Which has helped facilitate the people of the United States of America down the wrong rabbit hole. (All these physicians were instructed regarding Active and Passive Immunization in some form of Immunology 101 in Medical School.)

On March 2, 2020, President Trump should have been advised: (1) that polyclonal antibodies were available in the form of COVID-19 Convalescent Plasma, (2) that a National COVID-19 Convalescent *Plasma Drive* directed and administered by the American Red Cross or other blood banking entity should have been initiated, and (3) an Organized Federally directed EARLY (within 72 hours of diagnosis of COVID-19 in an infected individual) administrative TREATMENT should be afforded EVERY INFECTED MAN, WOMAN, and CHILD in the United States of America.

Table 1: Physicians present in *The White House* Conference on March 2, 2020 <https://www.c-span.org/video/?469926-1/president-trump-meeting-pharmaceutical-executives-coronavirus>

Robert Redfield, M.D., Director, CDC  
Anne Schuchat, M.D., Principal Deputy Director, CDC  
Deborah L. Birx, M.D., Coordinator, *The White House*, Coronavirus response  
Anthony S. Fauci, M.D., Director, NIAID  
Stephen Hahn, M.D., FDA Commissioner  
Leonard Schleifer, M.D., Ph.D., CEO and co-founder of Regeneron Pharmaceuticals  
Paul Stoffels, M.D., Chief Science Officer, Johnson & Johnson  
Mikael Dolsten, M.D., Ph.D., CEO, Novavax

- II. On March 13, 2020, President Trump proclaimed a national emergency concerning the novel coronavirus disease (COVID-19) outbreak.  
<https://trumpwhitehouse.archives.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/> Subsequent to this Proclamation of the same day and retroactive to March 1, 2020, U.S. Department of Health and Human Services Secretary Alex Azar issued a waiver or modification of requirements under Section 1135 of the Social Security Act which I allege became the *de facto* justification of abridgement of individual Americans' rights to ask for *Passive Immunization* and the antiviral drug Remdesivir guaranteed under EMTALA (the Emergency Medical Treatment and Labor Act of COBRA, Consolidated Omnibus Budget Act of 1986, PL-99-272), and the Right to Tray Act of 2018, PL-115-176.  
<http://www.phe.gov/emergency/news/healthactions/section1135/Pages/covid19-13March20.aspx> Mr. President, it is my impression that your administration renewed the *COVID-19 Emergency Declaration Blanket Waiver for Health Care Providers (COVID-19 EDBWHCP)* thus continuing the *de facto* EMTALA suspension on February 19, 2021. The above related story seems to corroborate my impression in practice as of last weekend.  
<https://web.archive.org/web/20210225112542/https://www.cms.gov/files/document/covid-19-emergency-declaration-waivers.pdf> The latest version of the **overwritten** of *COVID-19 EDBWHCP* states that these waivers will terminate at the end of the COVID-19 public health emergency (PHE). <https://www.cms.gov/files/document/covid-19-emergency-declaration-waivers.pdf> Well, Mr. President, when will the end of the COVID-19 public health emergency (PHE) be declared? Until the waivers of EMTALA are terminated, no American is guaranteed when they go to an ER that will be afforded their rights:
- i. To be stabilized on arrival to the ER
  - ii. To be diagnosed
  - iii. Appropriate disposition be afforded each and every patient, e.g.: treated appropriately and discharged appropriately after complete stabilization
- III. On March 19, 2020, Surgeon General Jerome Adams, M.D. in a PSA from *The White House* admonished all American the following:  
As the Nation's doctor, I often get asked: What should I do if I think I might have coronavirus? Well, it is important to know the symptoms--they include: fever, cough, and shortness of breath. If you are having these symptoms or worry you might have coronavirus, please call your healthcare provider.  
**We don't want you to go into the ER or the doctor's office without talking to them first because you might spread coronavirus to someone else.** They will help you think through and learn how to react including figuring out where to go to get tested if necessary.  
<https://www.facebook.com/WhiteHouse/videos/psa-if-you-are-sick/196091611816606/>
- IV. On March 19, 2020, Global Health NOW of Johns Hopkins Bloomberg School of Public Health ran an article: COVID-19's stop-gap solution until vaccines and antivirals are ready in which China had offered Italy 90 tons of COVID-19 Convalescent Plasma (~203,000 FFP units of COVID-19 Convalescent Plasma)  
<https://www.globalhealthnow.org/2020-03/covid-19s-stop-gap-solution-until-vaccines-and-antivirals-are-ready>

***How can plasma be useful against the novel coronavirus?***

*When you recover from many viral diseases, you have in your blood what are called neutralizing antibodies. These are antibodies that kill the virus. Once you recover, the plasma be taken from donors. It's very safe. It's the same thing as using a blood donation except they don't take the red blood cells, they take the liquid. They take the plasma. It is itself a drug...it can be used for prevention of infection for people who are being exposed or it could be used for therapy for those who are sick.*

*It's not a vaccine. Think about it as the administration of a protein, it's a liquid that is given to people that gives them immunity.*

***Right. Because the vaccine would provoke the recipient's antibodies. You'll have the antibodies, but they won't be your antibodies—though it'll do the same thing.***  
*Right.*

***And if somebody is already sick, can the plasma help them?***  
*Yes, it can be used for prevention or a treatment.*

***This strategy is already being used in China?***  
*Yes, in fact, the Chinese sent 90 tons of plasma to Italy.*

- V. On March 24, 2020, the FDA issued the following directive: Investigational COVID-19 Convalescent Plasma – Emergency INDs, March 24, 2020.  
[https://notifylibrary.org/sites/default/files/Investigational%20COVID-19%20Convalescent%20Plasma%20-%20Emergency%20INDs%20\\_%20FDA.pdf](https://notifylibrary.org/sites/default/files/Investigational%20COVID-19%20Convalescent%20Plasma%20-%20Emergency%20INDs%20_%20FDA.pdf) The FDA proposed inclusion criteria ***incorrectly*** directed / mandated administration of COVID-19 Convalescent Plasma only late in the disease (the cytokine cascade and the bradykinin storm) and not during the initial viremia of 72-120 hours after symptoms/diagnosis **WHICH FOR 120 YEARS HAS BEEN THE CORRECT TIME TO ADMINISTER ANY FORM OF CONVALESCENT PLASMA OR SERUM.** A completely unsubstantiated misinterpretation of a Chinese epidemiology article published in the *Journal of the American Medical Association* a month earlier was used by the FDA to justify this inclusion criteria. **THE APPLICATION OF THIS MISINTERPRETATION IS COMPLETELY BOGUS, IS BEING APPLIED EVEN TODAY in community practice, AND THE FDA AND THE NIH KNOW THAT IT IS WRONG!**  
<https://jamanetwork.com/journals/jama/fullarticle/2762130> The incorrect inclusion criteria is pervasive in practice even today has justified INCORRECT RATIONING of the antivirals and biologics. Officially, instead of the FDA and the NIH basing treatment on the Pathophysiology of COVID-19 and administering antivirals and biologics with 72 – 120 hours (the initial viremic period) from March 24, 2020 to August 28, 2020 and September 2, 2020, respectively wrong inclusion criteria was directed:

**Eligible patients for use under expanded access provisions:**

Must have laboratory confirmed COVID-19

Must have severe or immediately life-threatening COVID-19, for example:

Severe disease is defined as:

dyspnea,

respiratory frequency  $\geq 30/\text{min}$ ,

blood oxygen saturation  $\leq 93\%$ ,

partial pressure of arterial oxygen to fraction of inspired oxygen ratio

< 300, and/or  
lung infiltrates > 50% within 24 to 48 hours  
Life-threatening disease is defined as:  
respiratory failure,  
septic shock, and/or  
multiple organ dysfunction or failure  
Must provide informed consent

Rear Admiral Denise Hinton, the FDA Chief Scientist, removed the Eligibility Criteria for Remdesivir on August 28, 2020 and for COVID-19 Convalescent Plasma on September 2, 2020.

- VI. On April 4, 2020, was the first day of the FDA/Mayo Clinic COVID-19 Expanded Access Program administered by Michael Joyner, M.D. digitally preserved by the Internet Archive (Wayback Machine). **(The official FDA definition of Expanded Access is that all COVID-19 Convalescent Plasma (CCP) was administered under Compassionate Use which means the >94,000 CCP units can't be used for Randomized Controlled Trials (RCT) by the definition of the NIH and FDA and per section IV above, the >94,000 units of CCP were given at the WRONG time!)**  
<https://web.archive.org/web/20200404010134/https://www.uscovidplasma.org/>
- VII. On April 24, 2020, President Trump introduced the idea of intravenous disinfectants which overshadowed the conference and distracted the discussion in which Dr. Hahn mentioned Convalescent Plasma and other anti-viral therapies.  
<https://www.rev.com/blog/transcripts/donald-trump-coronavirus-press-conference-transcript-april-24>
- VIII. On May 1, 2020, President Trump in the Oval Office accepted the first shipment of the antiviral Remdesivir from the CEO of Gilead Sciences.  
Mr. O'Day, Gilead Sciences CEO: What I'd like to say is that, you know, on behalf of Gilead, to the President's point, we feel a tremendous responsibility. We're humbled by this being an important first step for patients, for hospitalized patients. We want to make sure nothing gets in the way of these patients getting the medicine. So we made a decision to donate about 1.5 million vials of remdesivir.

The administration of Remdesivir would be given **at the wrong time** – late in the disease in those individuals with severe disease--using the same incorrect FDA Inclusion Criteria for CCP from May 1, 2020 to August 28, 2020. FDA Chief Scientist Hinton from the Inclusion Criteria in the EUA of August 28, 2020, stated: "...FDA is reissuing the May 1, 2020 letter in its entirety with revisions incorporated to expand the authorized use of Veklury **by no longer limiting its use to the treatment of patients with severe disease.**"  
<https://web.archive.org/web/20200829175858/https://www.fda.gov/media/137564/download>

**On October 22, 2020, Remdesivir (Velkury) was designated by the FDA as a new prescription drug, NDA 214787.**

[https://www.accessdata.fda.gov/drugsatfda\\_docs/appletter/2020/214787Orig1s000ltr.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2020/214787Orig1s000ltr.pdf) In November 2020, the VA Pharmacy Benefits Management Services 10PAP, Medical

Advisory Board, and VISN Pharmacist executive **must not have read Rear Admiral Hinton's EUA revision of August 28, 2020**, and the Inclusion Criteria was based on the EUA of May 1, 2020:

### Inclusion Criteria

The following must be fulfilled to meet criteria for remdesivir  
Hospitalized with **SEVERE** COVID-19 (room air oxygenation saturation <94%, requiring supplemental oxygen or increase from baseline if on chronic oxygen therapy or is invasive or non-invasive ventilation or ECMO)\*\*\*

[https://vanf.app/CFU\\_PDF/Remdesivir\\_VEKLURY\\_November2020.pdf](https://vanf.app/CFU_PDF/Remdesivir_VEKLURY_November2020.pdf) This URL cannot be found today even with the Internet Archive which suggests that the VA removed the discoverability of this incorrect (**WRONG**) directive:

Remdesivir (VEKLURY) CFU

Remdesivir (VEKLURY) CFU

Remdesivir (VEKLURY) Criteria for Use November 2020
VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives
<i>The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of this document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&amp;T COMMITTEE AND PHARMACY SERVICES.</i>
The Product Information should be consulted for detailed prescribing information.
See the VA National PBM-MAP-VPE Monograph on this drug at <a href="http://www.pbm.va.gov">www.pbm.va.gov</a> or <a href="http://vaww.pbm.va.gov">http://vaww.pbm.va.gov</a> for further information.
<b>Exclusion Criteria</b>
If the answer to <b>ANY</b> item below is met, then the patient should <b>NOT</b> receive remdesivir
<input type="checkbox"/> Treated for COVID-19 as an outpatient
<input type="checkbox"/> AST or ALT > 5 times the upper limit of normal
<input type="checkbox"/> Hospitalized patients but NOT requiring supplemental oxygen*
<input type="checkbox"/> Concomitant use of hydroxychloroquine or chloroquine
<input type="checkbox"/> Current eGFR < 30 mL/min**
<b>Inclusion Criteria</b>
The following must be fulfilled in order to meet criteria for remdesivir
<input type="checkbox"/> Hospitalized with <b>SEVERE</b> COVID-19 (room air oxygen saturation < 94%, requiring supplemental oxygen or increase from baseline if on chronic oxygen therapy or is requiring invasive or non-invasive ventilation or ECMO)***
<b>Supplemental Information</b>
Recommended initial duration of therapy is 5 days, with the potential to extend to 10 days in patients who are not improving or who remain critically ill. Therapy can be discontinued when the patient is appropriate for discharge, even if the full duration of therapy has not been given
*Use in hospitalized patients with mild to moderate COVID-19 at high risk for progression to severe disease may be appropriate and should be adjudicated on a case by case basis
**Patients with eGFR < 30 mL/min (or CrCl < 30-50 mL/min depending on the trial) were excluded from clinical trials and routine use is not recommended by the manufacturer. Use may be considered and adjudicated on a case by case basis if the benefit is felt to outweigh the risks, especially when renal function is likely to improve rapidly (e.g. dehydration). The mechanism of calculating renal function can be based on local guidance.
***Remdesivir alone is not recommended alone for patients on mechanical ventilation or ECMO but may be considered in conjunction with corticosteroids in patients who have recently been intubated, according to the NIH Treatment Guidelines for COVID-19

Prepared: November 2020. Contact: Kelly Echevarria, PharmD, BCPS, AQ-ID, BCIDP, National Clinical Pharmacy Program Manager, VA Pharmacy Benefits Management Services 10P4P

Updated version may be found at [PBM.INTERnet](http://PBM.INTERnet) or [PBM.INTRAnet](http://PBM.INTRAnet)

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- IX. In the Summer of 2020, the FDA / Mayo Clinic Expanded Access Program (compassionate use only so no data can be used for Prospective Clinical Trials) issued two reports on the safety of COVID-19 Convalescent Plasma:

2020-05-14 Joyner MJ, Wright RS, Fairweather D, Senefeld JW, Bruno KA, Klassen SA, Carter RE, Klompas AM, Wiggins CC, Shepherd JRA, Rea RF, Whelan ER, Clayburn AJ, Spiegel MR, Johnson PW, Lesser ER, Baker SE, Larson KF, Ripoll JG, Andersen KJ, Hodge DO, Kunze KL, Buras MR, Vogt MNP, Herasevich V, Dennis JJ, Regimbal RJ, Bauer PR, Blair JE, Buskirk CMV, Winters JL, Stubbs JR, Paneth NS, Casadevall A: Early safety indicators of COVID-19 convalescent plasma in 5,000 patients. MedRxiv – Preprint May 12, 2020. <https://www.medrxiv.org/content/10.1101/2020.05.12.20099879v1.full.pdf> Ref 464

And

2020-07-19 Joyner MJ, Bruno KA, Klassen SA, Kunze KL, Johnson PW, Lesser ER, Wiggins CC, Senefeld JW, Klompas AM, Hodge DO, Shepherd JRA, Rea RF, Whelan ER, Clayburn AJ, Spiegel MR, Baker SE, Larson KF, Ripoll JG, Andersen KJ, Buras MR, Vogt MNP, Herasevich V, Dennis JJ, Regimbal RJ, Bauer PR, Blair JE, van Buskirk CM, Winters JL, Stubbs JR, van Helmond N, Butterfield BP, Sexton MA, Soto JCD, Paneth NS, Verdun NC, Marks P, Casadevall A, Fairweather D, Carter RE, Wright RS. COVID-19 Convalescent Plasma in 20,000 hospitalized patients. Mayo Clin Proc September 2020; 95(9): 1888-1897. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7368917/pdf/main.pdf> (ref 521)

Although these studies were funded by multiple agencies of the Federal Government, were listed on <https://clinicaltrials.gov/>, and COVID-19 Convalescent Plasma was deemed SAFE by these two studies, that “SAFETINESS” in 20,000 people under the guise of “compassionate use only” **disqualified the literal conclusion of a Phase I trial** and thus the Right to Try Act of 2018, (PL-115-176) was circumvented by the FDA and the NIH.

I submitted my analysis on 2020-06-08 to Dr. Fauci’s office:

**Andrus CH**: Time: The Crucial Independent Variable of the COVID-19 Pandemic, U.S. Copyright Office, Library of Congress, 2020-06-08, Txu002199029. [https://web.archive.org/web/20210904014401/https://cocatalog.loc.gov/cgi-bin/Pwebrecon.cgi?v1=9&ti=1%2C9&Search\\_Arg=Andrus+Charles+H&Search\\_Code=NALL&CNT=25&PID=DvTGOW\\_Qvd\\_foYxTFRVcdewL3ktMCwz&SEQ=20210425193720&SID=1](https://web.archive.org/web/20210904014401/https://cocatalog.loc.gov/cgi-bin/Pwebrecon.cgi?v1=9&ti=1%2C9&Search_Arg=Andrus+Charles+H&Search_Code=NALL&CNT=25&PID=DvTGOW_Qvd_foYxTFRVcdewL3ktMCwz&SEQ=20210425193720&SID=1)

Dr. Fauci turned over the material to Kara Harris to respond to me and in her response she established NIH NIAID Case #12276. (Ref 490 and also )

Possibly in response to my submission of June 8, 2020, eleven days later on the Friday afternoon of June 19, 2020, *The White House* Press Secretary, Ms. McEnany in the segment 42.55 minutes to 44.43 minutes of

<https://www.youtube.com/watch?v=GxX6CgI7RJ4> discussed COVID-19 Convalescent Plasma. **Mr. President**, please note that Ms McEnany is a lawyer and during this part of the News Conference seemed very uncomfortable announcing:

...Finally, well second, to finally, we are encouraged that we continue to gather positive data on a number of therapeutics: heparin; dexamethasone or steroids as it's more commonly known; convalescent plasma; and Remdesivir have all shown promise in treating coronavirus. Preliminary findings in a large UK-based recovery trial found that when steroids were used there was a 30% reduction in death for coronavirus patients on ventilators. The FDA is reviewing this recovery trial data now. Additionally, on convalescent plasma there's more encouraging news in partnership with Mayo Clinic the Trump administration move very quickly on this therapy and it's earliest days recognizing that it showed promise. Through the FDA Mayo Clinic and the administration's work in our hand-in-hand partnership, we found that this treatment is very promising--this has shown that the administration has left no stone unturned in looking at every possible treatment at the very early stages. The lead investigator of this Mayo Clinic study, Dr. Michael Joyner, summed up his work in saying that convalescent plasma "continues to look promising" noting the "excellent news of this study which covered a diverse population of patients about 20% were African-American, nearly 35% Hispanic, 5% Asian, and 40% women. Prior experience with respiratory viruses and some data that have emerged globally suggest convalescent plasma has the potential to lessen the severity or shorten the length of the illness caused by COVID-19. The results from the Mayo underscore that promise. As you can see, the Trump administration and FDA led on identifying convalescent plasma as a therapeutic and the results are encouraging...

(Ref 495)

On July 22, 2020, I submitted my next analysis: Andrus CH: The Mayo Clinic "Safety Update" should be classified as a completed Phase I trial of COVID-19 convalescent plasma. U.S. Copyright Office, 2020-07-22, TXu002214049.  
[https://web.archive.org/web/20210904020833/https://cocatalog.loc.gov/cgi-bin/Pwebrecon.cgi?v1=6&ti=1%2C6&Search\\_Arg=andrus+charles+h&Search\\_Code=NALL&CNT=25&PID=cXtFuGrmHQvLVlVfNNt7Yjwh73ImgQ&SEQ=20210512081428&SID=1](https://web.archive.org/web/20210904020833/https://cocatalog.loc.gov/cgi-bin/Pwebrecon.cgi?v1=6&ti=1%2C6&Search_Arg=andrus+charles+h&Search_Code=NALL&CNT=25&PID=cXtFuGrmHQvLVlVfNNt7Yjwh73ImgQ&SEQ=20210512081428&SID=1)

On July 30, 2020, Members of the COVID-19 *White House* Commission accompanied President Trump to the headquarters of the American Red Cross: President Trump visits the American Red Cross. To highlight need for convalescent plasma during COVID-19. (Ref 527) <https://www.redcross.org/about-us/news-and-events/press-release/2020/red-cross-highlights-need-for-convalescent-plasma-during-covid-19.html>

On the same day, FDA Commissioner Steven Hahn, M.D. released his PSA. (*An appeal by the FDA Commissioner on the same day as the American Red Cross visit by President Trump soliciting patients recovering from COVID-19 to donate COVID-19 Convalescent Plasma.*) <https://www.youtube.com/watch?v=PIX15rWdBbY>. (Ref 528) and Dr. Birx also suggests need for CCP: McKend E: Dr. Birx: Plasma donations needed as coronavirus cases spike nationwide.  
<https://spectrumnews1.com/ky/lexington/health/2020/07/30/dr--birx--plasma-donations-needed-as-coronavirus-cases-spike-nationwide> (Ref 530)

In early August 2020, multiple studies RECOMMENDED THE ADMINISTRATION OF CCP **EARLY** in the course of the disease after President Trump's visit to the American Red Cross:

On August 4, 2020: Dockser Marcus A: Convalescent plasma reduced death rate among Covid-19 patients, study data signals—Hospitalized patients who got earlier transfusions of blood plasma rich in antibodies to the coronavirus show a lower mortality rate. Wall Street Journal.

<https://www.wsj.com/articles/convalescent-plasma-reduced-death-rate-among-covid-19-patients-study-data-signals-11596594390> (Ref 536)

Hospitalized Covid-19 patients who received transfusions of blood plasma rich with antibodies from recovered patients reduced their mortality rate by about 50%, according to researchers running a large national study.

The researchers presented their data analysis Saturday in a webinar for physicians interested in learning about **so-called convalescent plasma**, with data slides that were reviewed by The Wall Street Journal. The researchers said they saw signs that the treatment might be working in patients who received high levels of antibodies in plasma early in the course of their illness. They based their conclusions on an analysis of about 3,000 patients.

Patients who at three days or less after diagnosis received plasma containing high levels of antibodies against the coronavirus had a mortality rate of 6.6% at seven days after the transfusion. That compared with a mortality rate of 13.3% for patients who got plasma with low levels of antibodies at four days or more after diagnosis. That indicates reduced mortality of about 50%, the researchers said.

At 30 days after transfusion, the mortality rate was reduced by about 36%, investigators reported

August 6, 2020: Hegerova L, Gooley TA, Sweerus KA, Maree C, Bailey M, Dunleavy V, Patel K, Alcom K, Haley R, Johnsen JM, Konkle BA, Lahti AC, Alexander ML, Goldman JD, Lipke A, Lim S, Pauk JS, Pagel JM: Use of convalescent plasma in hospitalized patients with COVID-19: case series. Blood 6 August 2020; 136 (6): 759-762. (ref 538)

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7414587/pdf/main.pdf>

In conclusion, the current study suggests that CP use in **severe and critically ill patients with COVID-19 may improve survival if given early in the course of disease**. The efficacy as a potential therapy needs further study in well-designed trials to better understand the contribution of CP to outcomes in COVID-19.

2020-08-06 Bloch EM: Convalescent plasma to treat COVID-19. Convalescent plasma to treat COVID-19. Blood 6 August 2020; 136 (6): 654-655. (Ref 539)

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7414591/pdf/main.pdf>

In conclusion, observational studies and compassionate use programs have been instrumental in the mobilization of CCP to contend with a global health emergency. Although safety has been addressed, efficacy data are critically needed to transition CCP's status from an investigational product to a standard therapy. The latter has practical ramifications, offering a formal mechanism for reimbursement and thus durable treatment strategy. Broadly, COVID-19 presents a rare opportunity to study

CP. If shown to be effective, CP would offer a scalable model that could be applied both to the current pandemic as well as to future emerging infectious diseases. It could also facilitate development of hyperimmune globulin and vaccine design. Clinical trials are already under way to address the uncertainty of use. Nonetheless, harmonization of efforts is needed along with creative approaches to overcome looming obstacles, such as pairing of trials of similar design and/or metanalysis. We must not be left wondering whether the intervention worked after the pandemic wanes.

2020-08-06 Xia X, Li K, Wu L, Wang Z, Zhu M, Huang B, Li J, Wang Z, Wu W, Wu M, Li W, Li L, Cai Y, Bosco B, Zhong A, Liu X, Lv T, Gan Z, Chen G, Pan Y, Liu C, Zhang K, Xu X, Wang C, Wang Q: Improved clinical symptoms and mortality among patients with severe or critical COVID-19 after convalescent plasma transfusion. *Blood* 6 August 2020; 136 (6): 755-758. (Ref 540)  
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7414593/pdf/main.pdf>

Experience from SARS-CoV-1 shows that convalescent plasma is most effective when administered shortly after symptom onset, typically within 2 weeks.<sup>7,14,17</sup> The study by Liu et al<sup>16</sup> showed that the effect of CCP was similar in an interval of 3 weeks' duration of symptoms. We compared the time to clinical improvement in patients with different therapy timings in our cohort, including 1 to 4 weeks, 5 to 6 weeks, 7 weeks, and 8 weeks after symptom onset. The results showed that the median time to clinical improvement was ;10 days in the 1 to 4 weeks', 5 to 6 weeks', and 7 weeks' groups. However, the time to clinical improvement was significantly prolonged in the \$8 weeks' group (Figure 1I).

In summary, we analyzed a large cohort of patients with COVID19 who received CCP and provide detailed evidence regarding their clinical improvement. Although the homogeneous data obtained from a single center may reduce some biases, there could inevitably be some confounding factors (eg, biased patient assignments) in this retrospective study. In addition, complete data on neutralizing antibody titers in CCP units were not available, limiting the power of evaluating the correlation between the quality of donor plasma and efficacy. Moreover, a stratified analysis of cases of severe and critical patients could not be performed due to the low proportion of critical patients. This analysis differs from existing studies in that its dynamic laboratory observations using large-scale data make it possible to analyze the potential therapeutic mechanism of CCP, recognize the characteristics of responders and nonresponders, and identify the indications and timing of therapy.<sup>18</sup> Our results suggest that CCP, transfused even after 2 weeks (median of 45 days in our cohort) of symptom onset, could improve the symptoms and mortality in patients with severe or critical cases of COVID-19. We anticipate that this study could shed new light in clinical practice and monoclonal antibody development for COVID-19.

2020-08-06. Tobian AA, Shaz BH: Earlier the better: convalescent plasma. *Blood* 6 August 2020; 136 (6): 652-653. (Ref 540)  
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7414595/pdf/main.pdf>

Convalescent plasma is one of the best therapies currently available to treat COVID-19. However, critical questions on timing of treatment in the disease course and dose (volume and antibody titer levels) need to be answered. These answers will also help prepare us for other passive antibody treatments (eg, hyperimmune globulin made from convalescent plasma and monoclonal antibodies). The medical community

must work together to battle this deadly disease in order to determine the best therapies and reduce mortality.

2020-08-07 U.S. Food & Drug Administration: Donate COVID-19 Plasma. (Ref 542) <http://web.archive.org/web/20200816041956/https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/donate-covid-19-plasma>

Anticipating that better access to COVID-19 (CCP) would be announced, a series of events that follow demonstrate how wrong CCP access was rolled out by the Trump Administration. In fact the referenced that follows should have been decried by every Institutional Review Board in the nation as what is implied is Unethical Coercion:

2020-08-12 Kozlov M: Two Washington U. doctors lead national effort to study new COVID-19 treatment. St. Louis Post-Dispatch Aug 12, 2020. (Ref 543) [https://www.stltoday.com/lifestyles/health-med-fit/coronavirus/two-washington-u-doctors-lead-national-effort-to-study-new-covid-19-treatment/article\\_ccec0f56-4493-5a26-8601-45e35d364b2d.html](https://www.stltoday.com/lifestyles/health-med-fit/coronavirus/two-washington-u-doctors-lead-national-effort-to-study-new-covid-19-treatment/article_ccec0f56-4493-5a26-8601-45e35d364b2d.html)

Since April, the Trump administration has set aside **more than \$300 million** to collect plasma and, with the Mayo Clinic, launch an experimental drug program, serving high-risk patients with few other treatment options. More than 60,000 have received plasma.

But the program has also had an unintended consequence: Patients aren't signing up for controlled trials, which compare outcomes for patients randomly assigned to receive the treatment with those who receive a placebo.

"If you have a 50% chance of getting either the stuff or nothing, which would you choose?" said Grossman, who is also director of transfusion medicine at Barnes-Jewish Hospital.

Moreover, clinical trials require thousands of patients, but the virus is spiking so quickly in communities, by the time doctors set up a trial, patients have disappeared.

Also on August 12, 2020, the FDA/Mayo Clinic Expanded Access Program announced, if given EARLY, that even in their "Compassionate Use" project patient mortality was significantly down: Joyner MJ, Senefeld JW, Klassen SA, Mills JR, Johnson PW, Theel ES, Wiggins CC, Bruno KA, Klompas AM, Lesser ER, Kunze KL, Sexton MA, Soto JCD, Baker SE, Shepherd JRA, van Helmond N, van Buskirk CM, Winters JL, Stubbs JR, Rea RF, Hodge DO, Herasevich V, Whenlan ER, Clayburn AJ, Larson KF, Ripoll JG, Andersen KJ, Buras MR, Vogt MNP, Dennis JJ, Regimbal RJ, Bauer PR, Blair JE, Paneth NS, Fairweather DL, Wright RS, Carter RE, Casadevall A: Effect of convalescent plasma on mortality among hospitalized patients with COVID-19: Initial three-month experience. Version 1. medRxiv Preprint. 2020 Aug 12. (Ref 544) <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7430623/?report=printable>

**Abstract** ...Participants: Adult participants enrolled and transfused under the purview of the US Convalescent Plasma EAP program between April 4 and July 4, 2020 who were hospitalized with (or at risk of) severe or life threatening acute COVID-19 respiratory syndrome. Intervention: Transfusion of at least one unit of human COVID-19 convalescent plasma using standard transfusion guidelines at any time during hospitalization. Convalescent plasma was donated by recently-recovered COVID-19 survivors, and the antibody levels in the units collected were unknown at the time of transfusion. Main Outcomes and Measures: Seven and thirty-day mortality. Results: the 35,322 transfused patients had heterogeneous demographic and clinical characteristics. This cohort included a high proportion of critically-ill patients, with 52.3% in the intensive care unit (ICU) and 27.5% receiving mechanical ventilation at the time of plasma transfusion. The seven-day mortality rate was 8.7% [95% CI 8.3-9.2%] in patients transfused within 3 days of COVID-19 diagnosis but 11.9% [11.4%-12.2%] in patients transfused 4 or more days after diagnosis ( $p < 0.0001$ ).

- X. When President Trump announced COVID-19 Convalescent Plasma (CCP) at the Sunday afternoon, August 23, 2020, *White House* press conference President Trump anticipated a bump in the poles prior to the next day's start of the Republican National Convention. Academic / University researchers / physicians within 24 hours criticized the announcement. References 551 to 553 in 20 2022-05-30 annotated Bibliographic Timeline References present the initial FDA response. In fact, the FDA released Reference **554** confirmed what the researchers in early August 2020 had already stated.

FDA News Release: FDA issues emergency use authorization for Convalescent Plasma as potential promising COVID-19 treatment, another achievement in Administration's fight against pandemic. U.S. Food & Drug Administration. <https://www.fda.gov/news-events/press-announcements/fda-issues-emergency-use-authorization-convalescent-plasma-potential-promising-covid-19-treatment>

Today, the U.S. Food and Drug Administration issued an emergency use authorization (EUA) for investigational convalescent plasma for the treatment of COVID-19 in hospitalized patients as part of the agency's ongoing efforts to fight COVID-19. Based on scientific evidence available, the FDA concluded, as outlined in its [decision memorandum](#), this product may be effective in treating COVID-19 and that the known and potential benefits of the product outweigh the known and potential risks of the product.

Today's action follows the FDA's extensive review of the science and data generated over the past several months stemming from efforts to facilitate emergency access to convalescent plasma for patients as clinical trials to definitively demonstrate safety and efficacy remain ongoing. The EUA authorizes the distribution of COVID-19 convalescent plasma in the U.S. and its administration by health care providers, as appropriate, to treat suspected or laboratory-confirmed COVID-19 in hospitalized patients with COVID-19.

**Alex Azar, Health and Human Services Secretary:**

"The FDA's emergency authorization for convalescent plasma is a milestone achievement in President Trump's efforts to save lives from COVID-19," said Secretary Azar. "The Trump Administration recognized the potential of convalescent plasma early on. Months ago, the FDA, BARDA, and private partners began work on making this product available across the country while continuing to evaluate data through clinical trials. Our work on convalescent plasma has delivered broader access to the product than is available in any other country and reached more than 70,000 American patients so far. We are deeply grateful to Americans who have already donated and encourage individuals who have recovered from COVID-19 to consider donating convalescent plasma."



**Stephen M. Hahn, M.D., FDA Commissioner:**

"I am committed to releasing safe and potentially helpful treatments for COVID-19 as quickly as possible in order to save lives. We're encouraged by the early promising data that we've seen about convalescent plasma. The data from studies conducted this year shows that plasma from patients who've recovered from COVID-19 has the potential to help treat those who are suffering from the effects of getting this terrible virus," said Dr. Hahn. "At the same time, we will continue to work with researchers to continue randomized clinical trials to study the safety and effectiveness of convalescent plasma in treating patients infected with the novel coronavirus."

*Scientific Evidence on Convalescent Plasma*

Based on an evaluation of the [EUA criteria](#) and the totality of the available scientific evidence, the FDA's Center for Biologics Evaluation and Research determined that the statutory criteria for issuing an EUA criteria were met.

The FDA determined that it is reasonable to believe that COVID-19 convalescent plasma may be effective in lessening the severity or shortening the length of COVID-19 illness in some hospitalized patients. The agency also determined that the known and potential benefits of the product, when used to treat COVID-19, outweigh the known and potential risks of the product and that there are no adequate, approved, and available alternative treatments.

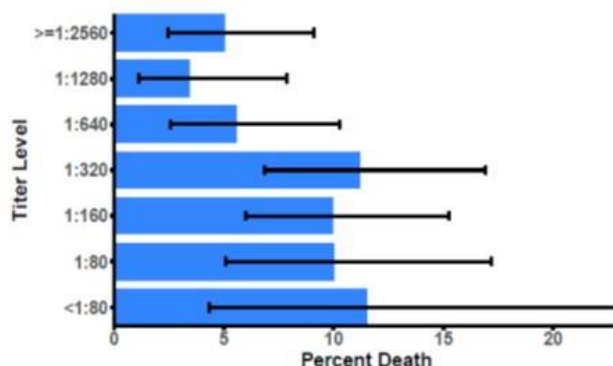
The EUA is not intended to replace randomized clinical trials and facilitating the enrollment of patients into any of the ongoing randomized clinical trials is critically important for the definitive demonstration of safety and efficacy of COVID-19 convalescent plasma. The FDA continues to recommend that the designs of ongoing randomized clinical trials of COVID-19 convalescent plasma and other therapeutic agents remain unaltered, as COVID-19 convalescent plasma does not yet represent a new standard of care based on the current available evidence.

The EUA remains in effect until the termination of the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biologics for prevention and treatment of COVID-19. The EUA may be revised or revoked if it is determined the EUA no longer meets the statutory criteria for issuance.

## COVID-19 Convalescent Plasma Reduction in Death at 7 Days

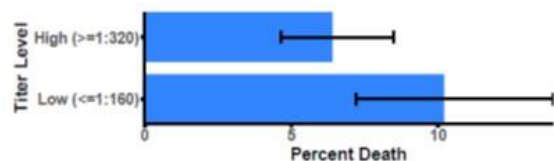


Non-intubated patients treated  
within 72 h age 80 or less (n=1018)



[www.fda.gov](http://www.fda.gov)

Statistically significant 37% reduction  
in mortality in those treated with high  
titer convalescent plasma ( $p=.03$ )



High titer corresponds  
approximately to Ortho  
VITROS S/C level  $\geq 12$

1

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products

While the FDA graphs above demonstrated that higher titer COVID-19 Convalescent Plasma was significantly effective ( $p=0.03$ ) in reducing mortality, the FDA, the NIH, and *The White House* **failed to delineate the significance of their graphic report**. What is worse, from High School Chemistry,  $C_1 \times V_1 = C_2 \times V_2$  corroborates that a doubling the volume administered to the patient will double the concentration (titer of immunoglobulins) circulating in the patient's serum. **For the last 25 months, the FDA has WRONGLY "emphasized" the Ultimate Importance of High Dose (HD) versus Low Dose (LD) COVID-19**. In fact, one can double, triple, or quadruple the titer just by adding additional volumes of COVID-19 Convalescent Plasma.

*Mr. President, PLEASE take it from this ABS certified General Surgeon, the only difference of the same volume of fresh frozen plasma (FFP) administered for clotting facts during an operation versus from fresh frozen of COVID-19 Convalescent Plasma (CCP) in the treatment of COVID-19 is that **CCP FFP** contains some concentration (titer) of Immunoglobulins directed specifically against antigens of Coronavirus, SARS-CoV-2.*

**Table 1: Conversion Low Dose COVID-19 Convalescent Plasma to High Dose COVID-19 Convalescent Plasma (CC-FFP) by increasing administration volume:**

Titer of a Dose (200 ml) of CC-FFP	C1: Relative Polyclonal Antibody Units (RPAU)	V1: Std Volume of CC-FFP (200 ml = 1/2 unit of CC-FFP)	C1 x V1= RPAU x 200 ml STD RPAU in STD VOL	C1 x V2= RPAU x 400 ml	C1 x V2= RPAU x 800 ml	C1 x V2= RPAU x 1600 ml
		std dose vol	RPAU x 200 ml = 1/2 unit of CC-FFP	RPAU x 400 ml = 1 unit of CC-FFP	RPAU x 800 ml = 2 units of CC-FFP	RPAU x 1600 ml = 4 units of CC-FFP
Very low titer -- <1:80 dilution	<80					
Low titer -- 1:80 dilution	80	200	16,000	32,000	64,000	128,000
Low titer -- 1:160 dilution	160	200	32,000	64,000	128,000	256,000
Low titer - 1:320 dilution	320	200	64,000	128,000	256,000	512,000
High titer -- 1:640 dilution	640	200	128,000	256,000	512,000	1,024,000
High titer -- 1:1280 dilution	1280	200	256,000	512,000	1,024,000	2,048,000
High titer -- $\geq 1:2560$ dilution	2560	200	512,000	1,024,000	2,048,000	4,096,000

The shaded areas represent "High Dose administrations" or conversions to "High Dose administrations" of COVID-19 Convalescent Plasma by infusing a full unit of CC-FFP, doubling the units administered or quadrupling the units administered (e.g.: 1 unit, 2 units, 4 units) so as to exceed threshold of survivability at a range of 3%-5% when the Relative Polyclonal Antibody

Units x volume equals or exceeds 128,000. Since September 2, 2020, the FDA, the NIH, etc. have touted to the American people that in fine print that: By the **EARLY** (<72 Hours from diagnosis) **TREATMENT** of a newly acquired infection of coronavirus SARS-CoV-2 (COVID-19) with High Dose COVID-19 Convalescent Plasma (CCP) **ONLY**: “HIGH DOSE COVID-19 Convalescent Plasma is BETTER than LOW DOSE COVID-19 Convalescent Plasma” with **better survival**. Thus, from the FDA’s graph above:

- (1) for (high dose) titers of 1:640 dilution to > 1:2560 dilution, **200 ml** (1/2 CC-FFP unit) IS MOST protective (more efficacious) titers (~3-5% death rate)
- (2) for an (intermediate dose) 1:320 dilution (~12% death rate), **400 ml** (1 CC-FFP unit) would be equivalent to the absolute neutralizing antibodies in 200 ml of a 1:640 dilution
- (3) for (low dose) titers of 1:160 and 1:80 dilutions (~10% death rate), **800 ml and 1600 ml, respectively** (2 CC-FFP units and 4 CC-FFP units, respectively) are adequate.

By increasing the administration volumes of Low Dose COVID-19 Convalescent Plasma or by concentrating (pooling multiple units) Low Dose COVID-19 Convalescent Plasma into COVID-19 Convalescent Serum, effective Passive Immunization with mortality rates of 4%-5% averaged across all age groups should have been accomplishable (from the FDA graph). Unfortunately, the FDA officially permitted administration of CC-FFP only in hospitalized patients; and the majority of the >772,000 CC-FFP doses all going to hospitalized patients were at the **WRONG TIME**--late in the disease--during the cytokine cascade and the bradykinin phases from at least April 2020 to the present. Can you imagine the decrease in mortality if the CC-FFP had been given HD **AS AN IMMEDIATE, EARLY TREATMENT FOR NEWLY DIAGNOSED COVID-19 in all patients with COVID-19 as is implied by the FDA in the graph above** !?!?!

In the letter: **1.0 2021-11-02 Dear Mr President Biden and ACS President Freischlag** within this present submission today, 9/22/2022:

*½ unit of (Fresh Frozen Plasma) FFP (1 “dose”) is ~200 ml; one unit of FFP is ~400 ml; and two units of FFP are ~800 ml. As a Vascular Surgeon, Dr. Freischlag-Julie, have you ever observed the unlikely fluid-overload of an adult patient strictly due to the tremendous volume of only 1 or 2 units (400 ml or 800 ml) of Fresh Frozen Plasma (FFP) administration? – I doubt it (Julie, please excuse my sarcasm as we surgeons have used FFP in blood component volume expansion when required throughout our professional lives with minimal complications.)!*

**In short, President Trump’s politicization of CCP gambit failed.**

Reference 558 explains why President Trump’s announcement backfired. By discontinuing the Mayo Clinic / FDA Expanded Access program, there was no easy, official mechanism in place for patients to just ask for COVID-19

Convalescent Plasma because **the FDA and NIH had been disregarding the implementation (and still are) of The Right to try Act of 2018 (PL-115-176):**

Gallagher C: Expanded access program for convalescent plasma discontinues enrollment as FDA authorizes its emergency use. Mayo Clinic News Network, August 23, 2020. <https://newsnetwork.mayoclinic.org/discussion/expanded-access-program-for-convalescent-plasma-discontinues-enrollment-as-fda-authorizes-its-emergency-use/>

2020-08-23 Andrus CH: Re: Thousands of Americans are *needless dying* because the FDA is illegally ignoring PL 115-176 – *The Right to Try Law*<sup>1,2</sup> and COVID-19 Convalescent Plasma has NOT been given as Prophylaxis and Early after COVID-19 positivity conversion. **Letter mailed to President Trump and the offices of the U.S. Senate.** [In the attached UHS-I Card: 06 Appendices A-H copy/01 Dear Members of Congress and President Trump 8\_23\_2020] I would also mailed 437 letters to the U.S. House of Representatives. While I did not received any responses, Rear Admiral Denise Hinton, R.N., M.S., FDA Chief Scientist removed the Severe Disease Inclusion Requirement for both COVID-19 Convalescent Plasma (CCP) and Remdesivir on September 2, 2020 and August 28, 2020, respectively.

(2020-08-28 **Andrus CH: Re:** This is a cover letter to the Congressional Staffer who will initially read the attached packet. After you read this cover letter, please bring it to your Chief of Staff so he or she might assess the importance of showing it to the Congressman or Congresswoman for whom you work. **Letter to the Offices of the U.S. House of Representatives.** [In the attached UHS-1 Card: 06 Appendices A-H copy/02 Dear Members of the US House of Representatives 8\_28\_2020])

2020-08-24 Thomas K, Fink S: F.D.A. ‘Grossly misrepresented’ blood plasma data, Scientists say. Many experts—including a scientist who worked on the Mayo Clinic study—were bewildered about where a key statistic came from. *The New York Times*  
<https://web.archive.org/web/20200825025014/https://www.nytimes.com/2020/08/24/health/fda-blood-plasma.html>

2020-08-24 Navarro P: Peter Navarro speaks with reports the day after the EUA announcement regarding COVID-19 Convalescent Plasma. <https://www.c-span.org/video/?475057-101/peter-navarro-speaks-reporters>

...kinds of successes he has last thing I want to do is talk a little bit about this cot convalescent plasma this is a great thing for the American people cob lesson plasma can reduce the mortality rate by 35 percent 35 percent and. If you see controversy in the news. You should think about this. There should absolutely be no controversy about convalescent plasma this is a therapy that's been used across many diseases for many decades the odds of it. Hurting you are close to 0 the odds of it helping you are close to 100 percent the only issue is how much it can help and according to the f.d.a. a 35 percent reduction in mortality so for me this convalescent plasma debate is in some sense a litmus test if you see anybody on c.n.n. or m s n b c or in the Democratic Party question the f.d.a. decision in any way all they are doing is politicizing this issue and at a cost of American lives we cannot afford in this

China virus debate to politicize or therapeutics in convalescent class by me if that's like going after Bambi you know this is the most one of the it's proven safe and effective Thank you all right. I'm a huge. Moment. For. You.

Is late in our judgment where we've been trying to do this for weeks simply with. I'm not I'm not I'm not privy to what the decisions were and what the data there was I haven't looked at that but I can I again I tell you this convalescent plasma is not on controversial it's been used for decades across many diseases. The odds of it hurting you are close to 0 the odds of it helping you are close to 100 percent this is the right to try president this is a time when Americans are dying and this is something that can be useful and so so look this timing issue again I think I think it's a way of people trying to politicize what shouldn't be politicized...

2020-08-25 Dockser Marcus A: Science Behind Convalescent Plasma for Covid-19 is Clouded by Politics in FDA Authorization. The Wall Street Journal Aug 25, 2020. [https://www.wsj.com/articles/fda-officials-reject-claims-that-convalescent-plasma-decision-was-politicized-11598362563?mod=article\\_inline](https://www.wsj.com/articles/fda-officials-reject-claims-that-convalescent-plasma-decision-was-politicized-11598362563?mod=article_inline)

- XI.** In October 2020, President Trump, former New York Mayor Rudy Giuliani, former New Jersey Governor Chris Christy, and former HUD Secretary Ben Carson, M.D. contracted COVID-19. All were given immunotherapy **IMMEDIATELY** in the form of monoclonal antibodies or monoclonal antibody cocktails and the antiviral Remdesivir. At the time, President Trump's physicians kept reiterating **the combination of an immunoglobulin and antiviral were EXPERIMENTAL when for the last century some form of immunoglobulins and antivirals are SYNERGISTIC and should be the STANDARD of CARE.**

2020-10-02 Homer M: Timeline: What we know about Regeneron's antibody cocktail that was given to President Trump. (Ref 602). <https://www.khou.com/article/news/health/coronavirus/trump-regeneron-polyclonal-antibody-cocktail/285-636b1f14-fed2-42f3-8b41-0a565a2dd967>

They are "a real best chance of being a game changer," NIH Director Francis S. Collins told the Washington Post about the experimental drug.

2020-10-05 Philippidis A, LeMieux J: Trump's treatments: Regeneron's antibodies and Gilead's Remdesivir explained. Genetic Engineering & Biotechnology News. (Ref 603) <https://www.genengnews.com/insights/trumps-treatments-regenerons-antibodies-and-gileads-remdesivir-explained/>

2020-10-05 LaMonica PR: Trump has ties to drugmaker Regeneron – and now its stock is surging. CNN Business. (Ref 604) <https://www.cnn.com/2020/10/05/investing/trump-regeneron/index.html>

**New York (CNN Business)** President Trump received a high dose of an experimental antibody cocktail from Regeneron as part of his Covid-19 treatment.

Now the drugmaker's stock is up sharply -- and questions are swirling about the president's ties to Regeneron's billionaire CEO.

Trump's team revealed Friday that the president received the drug, called REGN-COV2, which is being used to alleviate symptoms and reduce viral load. Shares of Regeneron surged 7% Monday, bringing the stock's year-to-date gain to more than 60%. The stock reached its highs of the day after Trump tweeted that he will be leaving the hospital Monday evening.

Regeneron CEO Dr. Leonard Schleifer and President Trump are acquainted: The CEO has been a member at Trump's golf club in Westchester, New York, and his company also received \$450 million in government funding in July as part of the president's Operation Warp Speed plan to quickly develop a vaccine and other treatments for Covid-19.

Meanwhile, Trump also recently owned shares of Regeneron (REGN) -- as well as Gilead Sciences (GILD), maker of the antiviral drug remdesivir that the president is also taking. Both stocks were listed as assets on Trump's 2017 filing with the U.S. Office of Government Ethics, though neither were holdings on the president's most recent filing for 2020.

"Len and President Trump are acquaintances from both living in the Westchester area for many years but didn't have any regular contact until this year, when they've discussed matters around Covid on occasion," Regeneron told CNN Business in a statement.

According to Forbes, Schleifer is now worth \$2.5 billion, up from \$2.1 billion in the middle of March. Schleifer primarily donated to Democratic political candidates and PACs in the 2016 and 2018 elections, according to Federal Election Commission records.

Regeneron is one of many biotechs and Big Pharma firms that has skyrocketed on hopes that it may be able to quickly develop an effective coronavirus treatment. The company started human trials for its antibody cocktail in June and began a phase 3 trial just a month later.

It has not yet been approved by the Food and Drug Administration, however. The FDA can approve the administration of it through so-called compassionate use requests on an individual basis. Regeneron confirmed to CNN Business that one of the president's doctors made such a request to Regeneron and the FDA to approve administering the drug to Trump.

Schleifer defended the decision to give Trump the cocktail last week, telling CNN's Wolf Blitzer that Trump "is in a higher-risk group for a variety of reasons" and that "we hope that we will give his immune system enough of a boost so that he can win this and make a complete recovery."

"We've got a lot of data, but we're still in the experimental phase. But when you're in the midst of a pandemic and you have people at risk, we think it makes sense to try these," Schleifer added.

Regeneron added in its statement to CNN Business that it is "in discussions with the FDA about potential for an Emergency Use Authorization for REGN-COV2" following the release of positive data about the drug last week.

The company had announced just a few days before President Trump's admission to Walter Reed that its cocktail "reduced viral load and the time to alleviate symptoms in non-hospitalized patients."

Regeneron said it is also in the process of studying the effect of the cocktail on hospitalized patients, as well as whether it can prevent infection in people who have been exposed to Covid-19.

Dr. George Yancopoulos, Regeneron's president and chief scientific officer, told CNN's Julia Chatterley in an interview Monday that the company is hoping it can get



more doses of REGN-COV2 to patients within the next few months thanks to a partnership with Big Pharma giant Roche.

"We are on track to deliver 300,000 doses by the end of the year and...produce 300,000 doses a month while the demand may even still exceed that," Yancopoulos said. "If the drug is really working and having the effects that we all hope it would, it could be doing a lot of good for a lot of people."

*Correction: An earlier version of this story misstated the compassionate use request process. One of the president's physicians made the request to Regeneron and the FDA.*

2020-10-05 Cohen J: Update: Here's what is known about Trump's COVID-19 treatment. Science. (Ref 605) <https://www.sciencemag.org/news/2020/10/heres-what-known-about-president-donald-trump-s-covid-19-treatment>

2020-10-05 Gringlas S, Sprunt B: Timeline: What we know of President trump's COVID-19 diagnosis, treatment. NPR. (Ref 606).  
<https://www.npr.org/sections/latest-updates-trump-covid-19-results/2020/10/03/919898777/timeline-what-we-know-of-president-trumps-covid-19-diagnosis>

- XII. The Scientists of both *Regeneron* and *Eli Lilly* recognized from their Clinical Trial data that the late administration of their monoclonal antibodies were not as effective as **EARLY (WITHIN 72-96 HOURS of diagnosis)**. Therefore, in the applications for the EUAs for both Regeneron's monoclonal antibody cocktail (two monoclonal antibodies) and Eli Lilly's monoclonal antibody, it was requested that it be stipulated that the monoclonal antibodies would be outpatient use but in a hospital-like setting for mild-to-moderate COVID-19 patients and not to be used for severe disease requiring respiratory support and ICUs. They suggested that patients with severe COVID-19 should be relegated to COVID-19 Convalescent Plasma treatment:

2020-10-07 Loftus P: Eli Lilly asks FDA to authorize Covid-19 antibody Drug. Wall Street Journal, Updated October 7, 2020, 11:31 pm ET. (Ref 611)  
<https://www.wsj.com/articles/eli-lilly-asks-fda-to-authorize-covid-19-antibody-drug-11602074998>

If cleared for use, the drug could be the first to treat less severe cases of Covid-19. The few other therapies authorized for Covid-19 treatment, including remdesivir from [Gilead Sciences Inc. GILD 1.41%](#) and [convalescent plasma](#), target hospitalized patients with more serious cases.

Lilly said it would seek authorization for use in higher-risk patients to prevent their recently diagnosed mild-to-moderate disease from worsening to a severe state. Executives of the Indianapolis-based company said higher-risk groups may include people 65 years of age or older or obese patients.

"Anything that helps with preventing hospitalization and preventing progression is going to be a big advance," Rajesh Tim Gandhi, an infectious-disease physician at Massachusetts General Hospital and Harvard Medical School, said in an interview.

Lilly's antibody drug could also be the first in a new class of Covid-19 agents that not only might provide treatment but also potentially give temporary protection

against the virus to people at risk of infection. That would [fill a gap until vaccines are authorized](#), though people may need to take the antibody drugs more than once to sustain the protection.

“When we started this project we always believed that vaccines would be a long-term solution but that antibodies could come to patients faster,” Lilly research head Daniel Skovronsky said in an interview. “We can make them faster, test them faster.”

The leading experimental antibody drugs have shown enough promise in testing so far that President Trump was [given one](#) developed by [Regeneron Pharmaceuticals](#) Inc.

Regeneron said Wednesday night it has asked the Food and Drug Administration to authorize use of its antibody drug cocktail for Covid-19. The company said it has supply for 50,000 patients available and will have 300,000 within a few months.

Lilly said last month [its drug reduced the rate of hospitalization](#) compared with a placebo in a study. About 1.6% were hospitalized or visited the emergency room for Covid-19 after being injected with the drug, compared with 5.8% of people who didn't get the drug in the study

2020-10-07 Gumbrecht J, Howard J: Eli Lilly seeks EUA from FDA to Covid-19 antibody treatment. CNN Health. The 3 minute 42 second video attached to this article is the most succinct overview of antibody therapies that should be employed in the treatment of COVID-19 regarding both **Passive Immunization** [the early administration of exogenous neutralizing antibodies to individuals (<72 hours of COVID-19 detection or prophylactically)] and **Active Immunization** [vaccination of an individual which is prevention after the ~ 2-3 week increasing development of neutralizing antibodies in the uninfected individual). (Ref 612). <https://www.cnn.com/2020/10/07/health/eli-lilly-antibody-therapy-results-eua/index.html>

2020-10-08 Beigel JH, Tomashek KM, Dodd LE, Mehta AK, Zingman BS, Kalil A, Hohmann E, Chu HY, Luetkemeyer A, Kline S, Lopez de Castilla D, Finberg RW, Dierberg K, Tapson V, Hsieh L, Patterson TF, Paredes R, Sweeney DA, Short WR, Touloumi G, Lye DC, Ohmagari N, Oh Myoung-don, Ruiz-Palacios GM, Benfield T, Fatkenheuer G, Kortepeter MG, Atmar RL, Creech CB, Lundgren J, Babiker AG, Pett S, Neaton JD, Bergess TH, Bonnett T, Green M, Makowski M, Osinusi A, Nayak S, Lane HC, for the ACTT-1 Study Group Members. Remdesivir for the treatment of Covid-19 – Final Report. NEJM.org, October 8, 2020. Published in harcopy N Engl J Med 2020; 383:1813-1826. November 5, 2020. A preliminary version of this article was published on May 22, 2020. (Ref 613) <https://www.nejm.org/doi/pdf/10.1056/NEJMoa2007764>.

### SAFETY OUTCOMES

In the as-treated population, serious adverse events occurred in 131 of 532 patients (24.6%) in the remdesivir group and in 163 of 516 patients (31.6%) in the placebo group (Table S17). There were 47 serious respiratory failure adverse events in the remdesivir group (8.8% of patients), including acute respiratory failure and the need for endotracheal intubation, and 80 in the placebo group (15.5% of patients) (Table S19). No deaths were considered by the investigators to be related to treatment assignment.

Grade 3 or 4 adverse events occurred on or before day 29 in 273 patients (51.3%) in the remdesivir group and in 295 (57.2%) in the placebo group (Table S18); 41 events were judged by the investigators to be related to remdesivir and 47 events to placebo (Table S17). The most common nonserious adverse events occurring in at least 5% of all patients included decreased glomerular filtration rate, decreased hemoglobin level, decreased lymphocyte count, respiratory failure, anemia, pyrexia, hyperglycemia, increased blood creatinine level, and increased blood glucose level (Table S20). The incidence of these adverse events was generally similar in the remdesivir and placebo groups.

Given the preliminary results about remdesivir, the Food and Drug Administration issued an Emergency Use Authorization on May 1, 2020 (modified on August 28, 2020), to permit the use of remdesivir for treatment in adults and children hospitalized with suspected or laboratory-confirmed Covid-19. Remdesivir has also received full or conditional approval in several other countries since that time. However, given high mortality despite the use of remdesivir, it is clear that treatment with an antiviral drug alone is not likely to be sufficient for all patients. Current strategies are evaluating remdesivir in combination with modifiers of the immune response (e.g., the Janus kinase [JAK] inhibitor baricitinib in ACTT-2, and interferon beta-1a in ACTT-3). A variety of therapeutic approaches including novel antivirals, modifiers of the immune response or other intrinsic pathways, and combination approaches are needed to continue to improve outcomes in patients with Covid-19.

- XIII. **Mr. President**, in late November 2020, I had elderly, debilitated patients with newly diagnosed urgent surgical problems (and now tested POSITIVE for COVID-19 when within the previous week they had been negative) admitted to the Unit II General Surgery (SLU) division, Surgical Service (112-jc), St. Louis VAMC of which I was the Chief Attending General Surgeon. Knowing the FDA admonishments (by omission) for **EARLY** administration (within 72-96 hours) of Remdesivir (August 28, 2020) and COVID-19 Convalescent Plasma (September 2, 2020), I immediately requested my residents write orders for both: a five-day course of Remdesivir and an infusion of COVID-19 Convalescent Plasma (CCP). Each of the patients received the one infusion of CCP without any difficulty. **BUT**, by the second dose of Remdesivir, the Chief of Infectious Diseases had ordered the Pharmacy to stop the continuation of the orders for Remdesivir citing the VACO directive of November 2020:

**On October 22, 2020, Remdesivir (Velkury) was designated by the FDA as a new prescription drug, NDA 214787.**

[https://www.accessdata.fda.gov/drugsatfda\\_docs/appletter/2020/214787Orig1s000ltr.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2020/214787Orig1s000ltr.pdf) In November 2020, the VA Pharmacy Benefits Management Services 10PAP, Medical Advisory Board, and VISN Pharmacist executive **must not have read Rear Admiral Hinton's EUA revision of August 28, 2020**, <https://web.archive.org/web/20200829175858/https://www.fda.gov/media/137564/download> and the Inclusion Criteria was based on the EUA of May 1, 2020:

#### **Inclusion Criteria**

The following must be fulfilled to meet criteria for remdesivir

Hospitalized with **SEVERE** COVID-19 (room air oxygenation saturation <94%, requiring supplemental oxygen or increase from baseline if on chronic oxygen therapy or is invasive or non-invasive ventilation or ECMO)\*\*\*

[https://vanf.app/CFU\\_PDF/Remdesivir\\_VEKLURY\\_November2020.pdf](https://vanf.app/CFU_PDF/Remdesivir_VEKLURY_November2020.pdf) This URL cannot be found today even with the Internet Archive which suggests that the VA removed the discoverability of this incorrect (**WRONG**) directive:

Remdesivir (VEKLURY) CFU

Remdesivir (VEKLURY) CFU

Remdesivir (VEKLURY) Criteria for Use November 2020
VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives
<i>The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&amp;T COMMITTEE AND PHARMACY SERVICES.</i>
The Product Information should be consulted for detailed prescribing information.
See the VA National PBM-MAP-VPE Monograph on this drug at <a href="http://www.pbm.va.gov">www.pbm.va.gov</a> or <a href="http://voww.pbm.va.gov">http://voww.pbm.va.gov</a> for further information.
<b>Exclusion Criteria</b>
If the answer to ANY item below is met, then the patient should NOT receive remdesivir
<input type="checkbox"/> Treated for COVID-19 as an outpatient
<input type="checkbox"/> AST or ALT > 5 times the upper limit of normal
<input type="checkbox"/> Hospitalized patients but NOT requiring supplemental oxygen*
<input type="checkbox"/> Concomitant use of hydroxychloroquine or chloroquine
<input type="checkbox"/> Current eGFR < 30 mL/min**
<b>Inclusion Criteria</b>
The following must be fulfilled in order to meet criteria for remdesivir
<input type="checkbox"/> Hospitalized with <b>SEVERE</b> COVID-19 (room air oxygen saturation < 94%, requiring supplemental oxygen or increase from baseline if on chronic oxygen therapy or is requiring invasive or non-invasive ventilation or ECMO)***
<b>Supplemental Information</b>
Recommended initial duration of therapy is 5 days, with the potential to extend to 10 days in patients who are not improving or who remain critically ill. Therapy can be discontinued when the patient is appropriate for discharge, even if the full duration of therapy has not been given
<i>*Use in hospitalized patients with mild to moderate COVID-19 at high risk for progression to severe disease may be appropriate and should be adjudicated on a case by case basis</i>
<i>**Patients with eGFR &lt; 30 mL/min (or CrCl &lt; 30-50 mL/min depending on the trial) were excluded from clinical trials and routine use is not recommended by the manufacturer. Use may be considered and adjudicated on a case by case basis if the benefit is felt to outweigh the risks, especially when renal function is likely to improve rapidly (e.g. dehydration). The mechanism of calculating renal function can be based on local guidance.</i>
<i>***Remdesivir alone is not recommended alone for patients on mechanical ventilation or ECMO but may be considered in conjunction with corticosteroids in patients who have recently been intubated, according to the NIH Treatment Guidelines for COVID-19</i>

Prepared: November 2020. Contact: Kelly Echevarria, PharmD, BCPS, AQ-ID, BCIDP, National Clinical Pharmacy Program Manager, VA Pharmacy Benefits Management Services 10P4P

Updated version may be found at [PBM.INTERnet](http://PBM.INTERnet) or [PBM.INTRANet](http://PBM.INTRANet)

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**Mr. President**, ironically while CCP was under an EUA, VELKURY (Remdesivir) had become a prescription drug (NDA 214787) on October 22, 2020. **Mr. President**, unfortunately, **NO ACCOUNTABLE PARTY IN VA CENTRAL OFFICE** seems to have ever read the revised EUA of Remdesivir of August 28, 2020, or the New Drug Application NDA# 214787 of October 22, 2020.

(**Mr. President**, VA Central Office is a ~five minute walk located at 810 Vermont Avenue, N.W. right across Lafayette Square from *The White House*.) I assume the nominal responsible parties of

the above **directive** of which can no longer be found on the Internet are: (1.) the VA Pharmacy Benefits Management Services, (2.) the VA Medical Advisory Panel, and (3.) VISN Pharmacist Executives. In December 2020, I contacted by e-mail VHA Chief Medical Executive Richard Stone, M.D. (had the authority of the VHA Under Secretary of Health) and the following correspondence ensued:

2020-12-13 2020-12-13 **Andrus CH**: Letter to the Editor of the New England Journal of Medicine regarding treatment with and synergy of ***Passive Immunization*** regarding the SARS-CoV-2 virus infection. \*\*\*The editors of NEJM ignored the letter but on January 6, 2021 published the landmark article (appropriately age stratified and COVID-19 Convalescent Plasma given within 72 hours of diagnosis): Libster, et. al.: Early high-titer plasma therapy to prevent severe Covid-19 in older adults, ClinicalTrials.gov, NCT04479163. New Engl J Med, NEJM.org, DOI: 10.1056/NEJMoa2033700, January 6, 2021, 1-9. (Ref 691)  
<https://www.nejm.org/doi/pdf/10.1056/NEJMoa2033700?listPDF=true>

2020-12-20 **Andrus CH**: E-mail submitted to Dr. Richard Stone, M.D., Chief Medical Executive (acting Under Secretary of the Veterans Health Administration), regarding the WRONG INCLUSION CRITERIA which contradicted the FDA directive of early administration in the course of COVID-19 disease (<72 hours from diagnosis) going forward from August 28, 2020 **to the present**, regarding Remdesivir (an FDA -approved licensed drug: NDA# 214787). This ERRONEOUS DIRECTIVE was still published on the Internet as of October 3, 2021—not having been retracted by the Veterans Health Administration (VHA)—**SHAME ON THE VHA!** The URL is no longer available.  
[https://vanf.app/CFU\\_PDF/Remdesivir\\_VEKLURY\\_November2020.pdf](https://vanf.app/CFU_PDF/Remdesivir_VEKLURY_November2020.pdf) What use to be at this U.S. Department of Veterans Affairs website is the following page that directed the administration of Remdesivir at the wrong time.

Remdesivir (VEKLURY) CFU

Remdesivir (VEKLURY) CFU

## Remdesivir (VEKLURY) Criteria for Use November 2020

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

*The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.*

The Product Information should be consulted for detailed prescribing information.

See the VA National PBM-MAP-VPE Monograph on this drug at [www.pbm.va.gov](http://www.pbm.va.gov) or <http://vawww.pbm.va.gov> for further information.

### Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive remdesivir

- ☐ Treated for COVID-19 as an outpatient
- ☐ AST or ALT > 5 times the upper limit of normal
- ☐ Hospitalized patients but NOT requiring supplemental oxygen\*
- ☐ Concomitant use of hydroxychloroquine or chloroquine
- ☐ Current eGFR < 30 mL/min\*\*

### Inclusion Criteria

The following must be fulfilled in order to meet criteria for remdesivir

- ☐ Hospitalized with SEVERE COVID-19 (room air oxygen saturation < 94%, requiring supplemental oxygen or increase from baseline if on chronic oxygen therapy or is requiring invasive or non-invasive ventilation or ECMO)\*\*\*

### Supplemental Information

Recommended initial duration of therapy is 5 days, with the potential to extend to 10 days in patients who are not improving or who remain critically ill. Therapy can be discontinued when the patient is appropriate for discharge, even if the full duration of therapy has not been given

*\*Use in hospitalized patients with mild to moderate COVID-19 at high risk for progression to severe disease may be appropriate and should be adjudicated on a case by case basis*

*\*\*Patients with eGFR < 30 mL/min (or CrCl < 30-50 mL/min depending on the trial) were excluded from clinical trials and routine use is not recommended by the manufacturer. Use may be considered and adjudicated on a case by case basis if the benefit is felt to outweigh the risks, especially when renal function is likely to improve rapidly (e.g. dehydration). The mechanism of calculating renal function can be based on local guidance.*

*\*\*\*Remdesivir alone is not recommended alone for patients on mechanical ventilation or ECMO but may be considered in conjunction with corticosteroids in patients who have recently been intubated, according to the NIH Treatment Guidelines for COVID-19*

Prepared: November 2020. Contact: Kelly Echevarria, PharmD, BCPS, AQ-ID, BCIDP, National Clinical Pharmacy Program Manager, VA Pharmacy Benefits Management Services 10P4P

Updated version may be found at [PBM.INTERnet](http://PBM.INTERnet) or [PBM.INTRANet](http://PBM.INTRANet)

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2020-12-24. **Andrus CH**: E-mail directed to the New England Journal of Medicine, the Veterans Health Administration, etc. It was ignored!

The following reference published on **January 6, 2021**, in *The New England Journal of Medicine* (NEJM) has gone unnoticed due the news distraction of the **Insurrection of January 6, 2021**. This was a landmark Randomized Control Trial from Argentina that demonstrated that when aged matched, COVID-19 Convalescent Plasma decreased significantly morbidity and decreased mortality but was not significant (due to the small size of the study).

2021-01-06 Libster R, Pérez Marc, Wappner D, Coviello S, Bianchi A, Braem V, Esteban I, Caballero MT, Wood C, Berrueta M, Rondan A, Lescano G, Cruz P, Ritou



Y, Fernández Viña V, Alvarez Paggi D, Esperante S, Ferreti A, Ofman G, Ciganda A, Rodriguez R, Lantos J, Valentini R, Itcovici N, Hintze A, Oyarvide ML, Etcegaray C, Neira A, Name I, Alfonso J, López Castelo R, Caruso G, Rapelius S, Alvez F, Etchenique F, Dimase F, Alvarez D, Aranda SS, Sánchez Yanotti C, De Luca S, Baglivo J, Laudanno S, Nowogrodzki F, Larrea R, Silveyra M, Leberzstein G, Debonis A, Molinos J, González M, Perez E, Kreplak N, Pastor Argüello S, Gibbons L, Althabe F, Bergel E, Polack FP, for the Fundación INFANT-COVID-19 Group\*: Early high-titer plasma therapy to prevent severe Covid-19 in older adults, ClinicalTrials.gov, NCT04479163. New Engl J Med, NEJM.org, DOI: 10.1056/NEJMoa2033700, January 6, 2021, 1-9. (Ref 707) <https://www.nejm.org/doi/pdf/10.1056/NEJMoa2033700?listPDF=true> Republished N Engl J Med, February 18, 2021; 384(7): 610 – 618.

2021-01-24 Face the Nation: Margaret Brennan interviews Deborah Birx, M.D. Face the Nation, CBSNews. The abridged version that aired on Face the Nation on Sunday morning, January 24, 2021: <https://www.youtube.com/watch?v=odklJGnhvhU> The complete interview of Dr. Birx by Margaret Brennan of Face the Nation of CBSNews: <https://www.youtube.com/watch?v=nW41YylWipM> (Ref 730)

2021-02-01 Andrus CH:

(Ref 738)

Dear Dr. Birx:

On March 24, 2020, while there was much discussion and debate about COVID-19 convalescent plasma and the possible development of monoclonal antibodies against COVID-19, U.S. Medicine and the Government failed to explain to the American public the differences and individual utilities of *Active Immunization* (vaccines to stimulate patient antibody production) and *Passive Immunization* (provision of convalescent plasmas, convalescence sera, and immunoglobins from other species providing already formed antibodies (IgM, IgG, and IgA) against the virus in COVID-19 immunologically naïve patients immediately within 72 hours of diagnosis (testing positive).

In your interview with Margaret Brennan, you stated the following:

DR. BIRX: Well, what I do know and what was reassuring to me all along is I knew this would be studied. I knew that the emails, the reports that I wrote, the request to expand testing, the **how to improve therapeutics**, all of that, all of that would eventually come to light. Maybe not in my lifetime.

Last summer you stated that we should collect 500,000 units of convalescent plasma to prepare for the spike in the Fall –well, we as a nation didn’t do that. In fact, as you are a clinical Immunologist, you are very well aware of ***Passive Immunization*** in the initial early treatment (<72 hours) with the contraction of or exposure to a disease without any true alternate therapy as soon as possible (<72 hours) [e.g.: rabies, hydrops fetalis (Rhogam within 72 hours to an Rh negative mother at delivery of the prior pregnancy, snake bites, etc)]. In fact, to withhold ***Passive Immunization*** (RhoGAM) from a newly delivered Rh negative mother is considered malpractice. By semantics and legal obfuscation, over the course of the last 10 months, the American public has been led down the rabbit hole by the Medical and Research community, the “Industry”, and the Federal Government by not officially providing any timely-appropriate immunotherapy in the treatment of COVID-19 positivity with ***Passive Immunization*** until recently:

1. In March 2020, the FDA declared COVID-19 Convalescent Plasma *Investigational* instead of a *Biosimilar* biologic;
2. On March 24, 2020 the FDA outlined ***Eligibility Criteria*** in the late treatment of severe COVID-19 disease with COVID-19 Convalescent Plasma (at deaths door – when the viremia is not the cause of death but rather the SARS pathophysiology) justifying this choice of late administration as the US did not have enough recovered convalescent patients (>14 days) ;
3. In early April 2020, the Mayo Clinic with the FDA offered COVID-19 Convalescent Plasma in the Expand Access protocol [Convalescent Plasma COVID-19 \(Coronavirus\) Treatment \(uscovidplasma.org\)](https://www.uscovidplasma.org/) using the at-deaths-door ***Eligibility Criteria*** (“expanded access” is really “compassionate use”—so, therefore, any resultant data cannot officially be used for completion of a Phase I Clinical Trial). Over 94,000 units of COVID-19 plasma were given AT THE THERAPEUTICALLY WRONG TIME only to severely-effected patients with the SARS pneumonitis or MSOF.
4. Throughout the last 11 months, the DHHS through the FDA and NIH has equated Safety Trials (Phase I trials) with Efficacy Trials (Phase II/III) so that there are no “Completed” Phase I (safety) trials with regards to COVID-19 biologics. Who should explain to the American people if the NIH plans on evading *ad infinitum* the “Right to Try” Law PL-115-176? Has not **a bad** precedent been set by not declaring a “completed” Phase I Trial with regards to COVID-19 Convalescent Plasma? Will any NIH protocol or FDA new drug/biologic Phase II/III trial and in any future research **not** be required to abide by the “Right to Try” Law, PL-115-176? In essence, the FDA and NIH are in violation, at least in violation of the intent of federal law PL-115-176 which requires a “Completed” Phase I Trial **only** for application of PL-115-176. Forcing patients to participate in Placebo-controlled Phase II/ III Trials is coercion which is prohibited by every IRB in the nation. On August 12,

2020 in the St. Louis Post-Dispatch, the following quote involving one of the FDA-Mayo Clinic's named investigators was documented:

But the program has also had an unintended consequence: Patients aren't signing up for controlled trials, which compare outcomes for patients randomly assigned to receive the treatment with those who receive a placebo.

"If you have a 50% chance of getting either the stuff or nothing, which would you choose?"

[https://www.stltoday.com/lifestyles/health-med-fit/coronavirus/two-washington-u-doctors-lead-national-effort-to-study-new-covid-19-treatment/article\\_ccec0f56-4493-5a26-8601-45e35d364b2d.html](https://www.stltoday.com/lifestyles/health-med-fit/coronavirus/two-washington-u-doctors-lead-national-effort-to-study-new-covid-19-treatment/article_ccec0f56-4493-5a26-8601-45e35d364b2d.html)

No IRB, worth their salt, should ever approve of such a concept of coercion in any Clinical Trial; and the FDA should not only shut down any Clinical Trial with such flagrant coercion but also censure, if not shut down, any IRB that permitted such coercion.

5. All summer, the FDA kept announcing they were close to releasing an EUA regarding COVID-19 Convalescent Plasma. President Trump went to the American Red Cross at the end of July confirming the need in his mind and that of the President's COVID-19 Taskforce for COVID-19 Convalescent Plasma. The announcement of the EUA was delayed until it would be announced on Sunday, August 23, 2020, by President Trump on the eve of the Republican National Convention. The next day, the NIH COVID-19 Guidelines Panel condemned the EUA for lacking scientific rigorous analysis (being based on Expanded Access/*Compassionate Use* protocol data from the FDA/Mayo clinic study). In the most-recent guidelines of the NIH COVID-19 Guideline Panel of January 14, 2021, the NIH COVID-19 Guidelines Panel is now hedging its bets by hiding under "Convalescent Plasma" *Last Update October 9, 2020*:

#### Rationale for Recommendation

Currently, there are insufficient data from well-controlled, adequately powered, randomized clinical trials to evaluate the efficacy and safety of convalescent plasma for the treatment of COVID-19. However, >70,000 patients in the United States have received COVID-19 convalescent plasma through the Mayo Clinic's Expanded Access Program (EAP), which was designed primarily to provide broad access to investigational convalescent plasma and thus did not include an untreated control arm. Both the Food and Drug Administration (FDA) and the Mayo Clinic performed retrospective, indirect evaluations of efficacy by using the Mayo Clinic EAP data, hypothesizing that patients who received plasma units with higher titers of SARS-CoV-2 neutralizing antibodies would have better clinical outcomes than those who received plasma units with lower antibody titers. **The results of their analyses suggest that convalescent plasma with high antibody titers may be more beneficial than low-titer plasma in nonintubated patients, particularly when administered within 72 hours of COVID-19 diagnosis.**

(While the Mayo Clinic's Expanded Access Program (EAP) did not have an official "untreated control arm" since it was *Compassionate Use* only, the Mayo Clinic's EAP Safety Update in June 2020 of 20,000 patients actually included a total of 21,987 infused patients with 1,987 patients not completing the post-infusion 7-day period and 8,130 being untreated. When one back-calculates varying the possible mortality rate in this untreated group, a mortality rate of 8.7% or greater would have been statistically significant with less than a 0.05% confidence level. *But, unfortunately, the Mayo Clinic's Expanded Access Program* did not even qualify as a "Completed Phase I Study" by the "purism" semantics of the NIH. Dr. Birx, the FDA has final statutory say over all new drugs and biologics, **NOT** the NIH.)

6. The Chief Scientist of the FDA, Rear Admiral Hinton, finally removed the severity criteria by removing completely the ***Eligibility Criteria*** regarding Remdesivir on August 28, 2020 (the VA Central Office pharmacy formulary panel was still insisting on the severity ***Eligibility Criteria*** as the only criteria for those eligible for Remdesivir in November 2020--three months after it was rescinded by Rear Admiral Hinton). [Veklury \(remdesivir\) EUA Letter of Approval, reissued 10/22/2020 \(fda.gov\)](#)
7. On September 2, 2020, the FDA removed completely without public awareness the severe disease ***Eligibility Criteria*** for COVID-19 Convalescent Plasma. Many institutions are still applying the severe disease ***Eligibility Criteria*** to this day--thus refusing patients COVID-19 Convalescent Plasma treatment when they first become COVID-19 positive and present to the local ER—including recently a patient with a 104 fever and uncontrollable cough that I personally know. (i.e.: The FDA's complete removal of the ***Eligibility Criteria*** after September 2, 2020 can be demonstrated by viewing an example of the U.S. Food & Drug Administration's website: *Recommendations for Investigational COVID-19 Convalescent Plasma* by comparing the most recent URL: <https://www.fda.gov/vaccines-blood-biologics/investigational-new-drug-ind-or-device-exemption-ide-process-cber/recommendations-investigational-covid-19-convalescent-plasma> by copying and pasting the URL into the Internet Archive (Wayback Machine) and displaying a URL before September 2, 2020 in which the severe disease ***Eligibility Criteria*** was outlined from April 2020 to September 2, 2020: [Recommendations for Investigational COVID-19 Convalescent Plasma | FDA \(archive.org\)](#) :

#### Patient Eligibility

To facilitate requests for eINDs for use of COVID-19 convalescent plasma to treat patients, health care providers seeking an emergency IND may want to consider the eligibility criteria used for the [National Expanded Access Treatment Protocol](#)[External Link Disclaimer](#). These criteria include:

- Laboratory confirmed COVID-19
- Severe or immediately life-threatening COVID-19, for example,
  - Severe disease is defined as one or more of the following:
    - shortness of breath (dyspnea),
    - respiratory frequency  $\geq 30/\text{min}$ ,

- blood oxygen saturation  $\leq 93\%$ ,
      - partial pressure of arterial oxygen to fraction of inspired oxygen ratio  $< 300$ ,
      - lung infiltrates  $> 50\%$  within 24 to 48 hours
    - Life-threatening disease is defined as one or more of the following:
      - respiratory failure,
      - septic shock,
      - multiple organ dysfunction or failure
  - Informed consent provided by the patient or healthcare proxy.
8. Before the EUAs were issued by Rear Admiral Hinton regarding the Regeneron monoclonal cocktail (casirivimab and imdevimab) and Eli Lilly monoclonal antibody bamlanivimab, on October 26, 2020 Eli Lilly asked the FDA to exclude the use of their monoclonal antibody in patients with any signs of severity of associated illness parameters such as any new requirement of oxygen supplementation in any non-COPD patient or increase in amount of oxygen supplementation in COPD patients.
9. Rear Admiral Hinton issued EUAs for Eli Lilly's bamlanivimab (<https://www.fda.gov/media/143602/download>) on November 10, 2020 and for Regeneron's casirivimab and imdevimab on November 21, 2020 (<https://www.fda.gov/media/143891/download>). Both EUAs state the following (I will use the Regeneron's monoclonal cocktail as the example as President Trump had received this "experimental" cocktail in early October 2020 prior to the issuing of these EUAs):

## II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited as follows:

- Distribution of the authorized casirivimab and imdevimab will be controlled by the United States (U.S.) Government for use consistent with the terms and conditions of this EUA. Regeneron will supply casirivimab and imdevimab to authorized distributor(s)<sup>4</sup>, who will distribute to healthcare facilities or healthcare providers as directed by the U.S. Government, in collaboration with state and local government authorities, as needed;
- The casirivimab and imdevimab covered by this authorization will be used only by healthcare providers to treat mild to moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progressing to severe COVID-19 and/or hospitalization;
- Casirivimab and imdevimab may only be administered together;
- **Casirivimab and imdevimab is not authorized for use in the following patient populations <sup>5</sup>:**
  - **Adults or pediatric patients who are hospitalized due to COVID-19, or**
  - **Adults or pediatric patients who require oxygen therapy due to COVID19, or**
  - **Adults or pediatric patients who require an increase in baseline oxygen flow rate due to COVID-19 in those patients on chronic**

**oxygen therapy due to underlying non-COVID-19-related comorbidity.**

- Casirivimab and imdevimab may only be administered in settings in which health care providers have immediate access to medications to treat a severe infusion reaction, such as anaphylaxis, and the ability to activate the emergency medical system (EMS), as necessary.
- The use of casirivimab and imdevimab covered by this authorization must be in accordance with the dosing regimens as detailed in the authorized Fact Sheets.

10. On November 24, 2020, in *NEJM* was published: Simonovich VA, *et al*: [A Randomized Trial of Convalescent Plasma in Covid-19 Severe Pneumonia \(nejm.org\)](#) which is an outstanding, well-thought-out prospective trial using the discontinued/withdrawn severely-ill COVID-19 patient ***Eligibility Criteria*** in which all COVID-19 Convalescent Plasma was given only in patients with severe COVID-19 SARS pneumonitis. Unfortunately, the authors failed to mention in their paper's abstract conclusion that the outcome of the study was based on patients given COVID-19 Convalescent Plasma with only severe SARS pneumonitis—following the previously omitted (September 2, 2020) severe patient *Eligibility Criteria* in which ***Passive Immunization*** was administered at the **WRONG TIME**—that is at deaths-door instead of within 72-hours of COVID-19 positivity!:

**CONCLUSIONS**

No significant differences were observed in clinical status or overall mortality between patients treated with convalescent plasma and those who received placebo. (PlasmAr ClinicalTrials.gov number, **NCT04383535. opens in new tab.**)

11. I wrote a Letter to the Editors of *The New England Journal of Medicine (NEJM)* regarding Simonovich VA, *et al* and included those I could access with regards to e-mails in the DHHS, the VA, and Saint Louis University SOM as I am a Professor of Surgery and the General Surgery Residency site director at the St. Louis (John Cochran) VAMC. I never got a response back from the *NEJM* but on January 6, 2021, the landmark article by Libster R, *et al*: [Early High-Titer Plasma Therapy to Prevent Severe Covid-19 in Older Adults \(nejm.org\)](#) demonstrated a statistically significant decrease in mortality and severity of illness in a specific age group (the elderly) when COVID-19 Convalescent Plasma was given within 72 hours (**AT THE RIGHT TIME**) of detection of COVID-19 positivity. As is stated in the conclusion of the abstract in this article:

**CONCLUSIONS**

Early administration of high-titer convalescent plasma against SARS-CoV-2 to mildly ill infected older adults reduced the progression of Covid-19. (Funded by the Bill and Melinda Gates Foundation and the Fundación INFANT Pandemic Fund; Dirección de Sangre y Medicina Transfusional del Ministerio de Salud number, PAEPCC19, Plataforma de Registro Informatizado de Investigaciones en Salud number, 1421, and ClinicalTrials.gov number, NCT04479163.)



One of my fellow Attending Surgeons at the VA came to my office after my e-mail cover letter to my Letter to the Editors to *NEJM* and stated that I had every right under the first Amendment to communicate whatever I wished but I was just making a fool of myself as there were much smarter people than me involved in setting standards for COVID-19 therapy. The next night, I got a call from an administrator at Saint Louis University SOM (SLUSOM) stating I was only allowed to speak about COVID-19 Convalescent Plasma with other faculty members of SLUSOM and the physicians, nurses, and other healthcare personnel at the local VA--St. Louis (John Cochran) VAMC and to STOP calling Washington DC. He then asked me unknowingly why I had included e-mails to Harvard. I responded that this e-mail was concerned my cover letter regarding my letter to the Editors of *The New England Journal of Medicine*. He responded: Oh—speak only with those in the local VA and Saint Louis University.

[Please note I attached a slide of mortality due to COVID-19 by age range between March and November 2020. First, the mortality percentages by age range had not changed over those 9 months suggesting the USA has not diminished the death rate by any therapy employed so far in any age group over 40 years of age. Second, you will note, the mortality from 40 to 90 years increases by 0.67% per year:  $y = 0.0067x - 0.2647$ ,  $R^2 = 0.9676$ ; and, below age 40, the mortality rate increases only by 0.04% per year to maximally 0.12%/year:  $y = 0.0004x - 0.0023$ ,  $R = 0.7987$ . Once again, as the mortality rates in all range groups over the age of 40 have not changed over the last 10 months, the late administration of **Passive Immunization** to the majority of the hundred thousand patients that received COVID-19 Convalescent Plasma was given at the WRONG TIME using the now rescinded FDA patient **Eligibility Criteria**--such administration at the WRONG TIME did not make a substantial impact. What this also implies is that sending the children and young adults back to in-school-learning will be relatively safe for the children—mortality rate 0.04% increase per year when compared with adults over age 40 years—mortality rate 0.67% per year (which is 16x higher than in children). This presents the possibility to generate a vector repository in our children who could then transmit COVID-19 to their parents, grandparents, and other adults who have a higher risk of severity of disease and death.]

12. The *NEJM* landmark article of January 6, 2021 by Libster R, *et al*: [Early High-Titer Plasma Therapy to Prevent Severe Covid-19 in Older Adults \(nejm.org\)](https://www.nejm.org/doi/full/10.1056/NEJMoa2025384) was overshadowed by the events that occurred later in the day in Washington D.C. Ironically, on January 14, 2021, *USA Today* ran an article: Rodriguez A: US officials urge Americans to ask their doctors about monoclonal antibodies for COVID. But is it too little, too late? [Monoclonal antibodies for COVID in full supply, but lack demand: HHS \(usatoday.com\)](https://www.usatoday.com/story/health/2021/01/14/monoclonal-antibodies-covid-19/7000000002/). On January 17, 2021 in *Infection Control Today*, Kavanagh K: [As Vaccine](https://www.infectioncontroltoday.com/news/as-vaccine)

[Rollout Stalls, Move Monoclonal Antibodies Into COVID Fight \(infectioncontroltoday.com\)](https://infectioncontroltoday.com)

using monoclonal antibodies used prophylactically to protect in exposures. **Both** monoclonal antibodies and COVID-19 Convalescent Plasma are **Passive Immunization** therapeutic agents and should therefore be administered at the same appropriate time--<72 hours from symptomatology or COVID-19 positivity instead of only to patients at deaths-door. Over the last 10 months, the American public has been so misdirected (or lied to) by the ambiguity in the terminology and focus on vaccine production that few realize that **Passive Immunization** includes polyclonal antibodies (COVID-19 Convalescent Plasma) and monoclonal antibodies which should be given to all immediately when they become COVID-19 positive!

13. As is now being reported in the press, mutations of COVID-19 are developing around the World that may make the present vaccines and monoclonal antibodies ineffective.

14. As we go forth, the Standard-of-Care should be the following:

A. For those of the present 330 million Americans that are not yet infected (immunologically naïve to the disease – COVID-19 negative), they should all be encouraged to receive one of the COVID-19 vaccines.

B. Every American who has had COVID-19 and is recovered by at least 14 days should be encouraged to donate COVID-19 Convalescent Plasma. <https://www.aabb.org/for-donors-patients/give-blood>

C. Every American who turns COVID-19 positive or becomes symptomatic (even if they have received a COVID-19 vaccine), should be afforded some form of **Passive Immunization** by the early-in-disease treatment COVID-19 Convalescent Plasma/Sera or Monoclonal Antibodies

D. As the COVID-19 mutations spread and the vaccines may be less effective, every American who turns COVID-19 positive or becomes symptomatic should be afforded **Passive Immunization** of COVID-19 Convalescent Plasma/Sera matching the COVID-19 mutation. Waiting for the development of a vaccine (or monoclonal antibodies) specific for the new COVID-19 mutation and withholding mutation specific COVID-19 Convalescent Plasma would be unconceivable and tantamount to patient abandonment. Every time the coronavirus mutates, it will take months to develop a new vaccine or a new monoclonal antibody—yet convalescent plasma effective against every next mutation will be available 14 days after the first human recovers

from each new mutation of the coronavirus through plasmapheresis donation.

E. When Kidney Transplantation was considered *Investigational* in the 1960s and 1970s and the insurance industry would not pay for Kidney Transplantation as it was “Experimental”, the Congress permitted for two decades the Attending Surgeons of Washington University SOM (Drs. Newton and Anderson) and Saint Louis University SOM (Drs. Maginn, Codd, and Garvin) to perform kidney transplants on both Veterans and civilians at the John Cochran (St. Louis) VAMC. Thus, the precedent six decades ago was set to employ the largest federal hospital system (both hospitals and CBOCs) in the nation of the Veterans Health Administration (VHA) to establish infusion centers to provide ***Passive Immunization*** in the treatment of COVID-19 for both Veterans and civilians.

F. Thomas Jefferson’s replacement of John Locke’s “property” with “the pursuit of happiness” in the *Declaration of Independence* was no mistake. We as American physicians should be leery of any potential inherent conflict-of-interest of *Industry’s* and *Medicine’s* working together possibly to the detriment of our patients. *De facto*, Medicine, the U.S. Government, and most of the World have publicly discredited polyclonal COVID-19 Convalescent Plasma (and Sera) while elevating monoclonal antibodies as viable early treatments in COVID-19 positivity—they are both ***Passive Immunization*** therapies. Every time the coronavirus mutates, it will take months to develop a new vaccine or a new monoclonal antibody—yet convalescent plasma effective against every next mutation will be available 14 days after the first human recovers from each new mutation of the coronavirus through plasmapheresis donation. The present situation throughout the World today is analogous to that of the mythological Sisyphus pushing the rock up the hill only for it upon nearing the top of the hill rolling back down for eternity.

After having viewed the abridged version of your interview on January 24, 2020 ([Full interview: Dr. Deborah Birx on "Face the Nation" - YouTube](#)) with Margaret Brennan, in my eyes you have throughout your professional life been a dedicated Military and Civil Service physician for individual patients and patients in the aggregate. Both you and I are professionally of the same generation. When we graduated, you from Penn State Univ SOM in 1980 and I in 1979 from Saint Louis Univ SOM, we both swore *Primum non Nocere* in the care of all of our patients throughout our future lives as physicians. As I viewed the interview last Sunday, I saw a physician who loves her country and has dedicated her life as a physician to bettering all patients’ lives. It is your duty, my duty, and all physicians’ duty by our oaths of *Primum non Nocere* to advocate for not just the preventative measures of

**Active Immunization** but also all potential therapeutic measures of **Passive Immunization**.

It would be my hope that this correspondence will be your introduction to President Biden to explain your suggestions and thoughts on our future therapy—**both Active Immunization and Passive Immunization**-- for all Americans. As Dr. Fauci is the President's Chief Medical Advisor on the USA COVID-19 epidemic, I will forward this letter to him, the NIH, and the FDA to help facilitate your meeting with the President. My previous Letter to the Editor of *The New England Journal of Medicine* has not been published but was probably partially the impetus for the *NEJM* publishing on January 6, 2021-01-06: Libster R, *et al*: [Early High-Titer Plasma Therapy to Prevent Severe Covid-19 in Older Adults \(nejm.org\)](https://www.nejm.org/doi/full/10.1056/NEJMe2020352) I will be sure to include the Editors of the *New England Journal of Medicine* in this correspondence today. Over the past year, I have submitted three items (listed below) to the U.S. Copyright Office of the Library of Congress to preserve the chronology of what has occurred for history. With any and all of my correspondence regarding our present COVID-19 epidemic, I will dutifully provide all that is asked of me by the U.S. Federal Government as it is my duty as a physician and surgeon of the Veterans Health Administration, U.S. Department of Veterans Affairs.

1. Andrus CH: *Time*: The Crucial Independent Variable of the COVID-19 Pandemic. U.S. Copyright Office, June 8, 2020. TXu002199029
2. Andrus CH: Mayo Clinic "Safety Update" should be Classified as a Completed Phase I Trial of COVID-19 Convalescent Plasma. July 22, 2020. TXu002214049
3. Andrus CH: 1 Dear Mr. President PLEASE COVID-19 Convalescent Plasma NOW 11-17-2020. November 18, 2020. TXu002232947

On the evening of January 20, 2021, the America public was reminded of past Presidential inaugural addresses:

President Abraham Lincoln's 2<sup>nd</sup> Inaugural Address includes the lines that I, as a VA physician and surgeon, and we as Americans have promised:

With malice toward none; with charity for all; with firmness in the right, as God gives us to see the right, let us strive on to finish the work we are in; to bind up the nation's wounds; **to care for him who shall have borne the battle, and for his widow, and his orphan**; to do all which may achieve and cherish a just, and a lasting peace, among ourselves, and with all nations.

That night, the most famous line of President Kennedy's was part of what was recited: "And so, my fellow Americans: ask not what your country can do for you—ask what you can do for you country." Dr. Birx, both you and I were in grammar school when the final lines were spoken that are most *apropos* to our present crisis and that for all time:

My fellow citizens of the world: ask not what America will do for you, but what together we can do for the freedom of man.

Finally, whether you are citizens of America or citizens of the world, ask of us here the same high standards of strength and sacrifice which we ask of you. With a good conscience our only sure reward, with history the final judge of our deeds, let us go forth to lead the land we love, asking His blessing and His help, but knowing that here on earth God's work must truly be our own.

Dr. Birx: Godspeed.

Respectfully,

Charles H. Andrus, M.D., F.A.C.S.

Professor, Department of Surgery, Saint Louis University School of Medicine  
Chief, Unit II General Surgery (SLU GS division), St. Louis (John Cochran division)  
VAMC

Home: 314-455-9482; home e-mail: candrus600@aol.com

Beeper: 314-491-2417

My wife's, Pamela Bergkamp Andrus's, cell phone: 314-809-9634

Within 48 hours, Rear Admiral Denise Hinton, R.N., M.S., revised the EUA for COVID-19 Convalescent Plasma.

2021-02-02 U.S. Food & Drug Administration: CLINICAL MEMORANDUM, EUA 26382, COVID-19 Convalescent Plasma (CCP). **NONE OF THE VERSIONS OF THESE MEMOS are dated and thus dating was obtained from the digital captures using the Internet Archive (WayBack Machine).** The URL of this Memorandum is: <https://www.fda.gov/media/141480/download> (Ref 739)

**From September 1, 2020 to at least February 2, 2021 was the first iteration/rough draft** to justify Hinton's reissuing the CCP EUA in November 2020 and then probably (the Wayback Machine has no digital captures from Feb 2 to Feb 15) the first major revision on February 4, 2021, of the CCP EUA of August 23, 2020 which was the first EUA regarding COVID-19 Convalescent Plasma issued by the FDA after the press conference announcement by President Trump of that day: Sunday, August 23, 2020—the day prior to the start of the Republican National Convention. Coincidentally, this **six-month draft** was the CLINICAL MEMORANDUM probably used to justify RADM Hinton's EUA of February 4, 2021 which was 48-72 hours after Dr. Andrus' Letter to Dr. Deborah Birx of February 1, 2021. As this first iteration of the MEMO regarding EUA 26382 was a draft, it lacks (1) the name of the individual who wrote it; (2) the name of the individual to whom it is written; and (3) the names of the FDA division chiefs through which the memo would pass. It does list the Sponsor, Robert Kadlec,

M.D., to whom all EUAs previously have been issued regarding Remdesivir, Monoclonal Antibodies/Antibody Cocktails, and COVID-19 Convalescent Plasma (CCP).

<https://web.archive.org/web/20210202143902/https://www.fda.gov/media/141480/download> The Executive Summary of the CLINICAL MEMORANDUM of September 1, 2020 through at least February 2, 2021:

EXECUTIVE SUMMARY COVID-19 Convalescent Plasma (CCP), an unapproved biological product, is proposed for use under an Emergency Use Authorization (EUA) under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act), (21 USC 360bbb-3) as a passive immune therapy for the treatment of hospitalized patients with COVID-19, a serious or life-threatening disease. There currently is no adequate, approved, and available alternative to CCP for treating COVID-19. The sponsor has pointed to four lines of evidence to support that CCP may be effective in the treatment of hospitalized patients with COVID-19: 1) History of convalescent plasma for respiratory coronaviruses; 2) Evidence of preclinical safety and efficacy in animal models; 3) Published studies of the safety and efficacy of CCP; and 4) Data on safety and efficacy from the National Expanded Access Treatment Protocol (EAP) sponsored by the Mayo Clinic.

Considering the totality of the scientific evidence presented in the EUA, I conclude that current data for the use of CCP in adult hospitalized patients with COVID-19 supports the conclusion that CCP meets the “may be effective” criterion for issuance of an EUA from section 564(c)(2)(A) of the Act. It is reasonable to conclude that the known and potential benefits of CCP outweigh the known and potential risks of CCP for the proposed EUA. Current data suggest the largest clinical benefit is associated with high-titer units of CCP administered early in the course of disease. Adequate and well-controlled randomized trials remain necessary for a definitive demonstration of CCP efficacy and to determine the optimal product attributes and appropriate patient populations for its use.

**Recommendation:** CCP meets the eligibility criteria for EUA under section 564 of the Act.

**February 15, 2021 was the first digital capture of the second iteration** to justify the ongoing EUAs of COVID-19 Convalescent Plasma (CCP) upgrades by RADM Hinton. As this second iteration of the MEMO regarding EUA 26382 does not seem to be a draft, it contains (1) the name of the individual who wrote it; (2) the name of the individual to whom it is written; and (3) the names of the FDA divisions chiefs through which the memo would pass. It does not list the Sponsor (not yet appointed by the Biden administration and confirmed) to whom all EUAs will be issued regarding Remdesivir, Monoclonal Antibodies/Antibody Cocktails, and COVID-19 Convalescent Plasma (CCP).

<http://web.archive.org/web/20210215192634/https://www.fda.gov/media/141480/download> The Executive Summary of the CLINICAL MEMORANDUM from February 15, 2021 to at least April 23, 2021 (the last digital capture by the WayBack Machine) to be unchanged:

## EXECUTIVE SUMMARY



COVID-19 Convalescent Plasma (CCP) was granted Emergency Use Authorization (EUA) for the treatment of hospitalized patients with COVID-19 on August 23, 2020. At that time, the totality of the scientific evidence supported a determination that the use of CCP in hospitalized patients with COVID-19 met the “may be effective” standard for issuance of an EUA, and it was reasonable to consider that the known and potential benefits of CCP outweighed the known and potential risks for the authorized use.

Following the EUA, emerging evidence from randomized controlled trials has continued to inform this assessment. The available evidence indicates that 1) the use of low titer CCP in hospitalized patients no longer meets the evidentiary standard of “may be effective”, and 2) high titer CCP has not demonstrated benefit when administered late in the disease course in immunocompetent hospitalized patients.

Additional data from RCTs and observational studies support a determination that high titer CCP may be effective when administered early in the course of illness, particularly prior to the expected time of host antibody response. In patients with impaired humoral immunity, the potential therapeutic window may be prolonged. As RCT data continue to demonstrate that the risks of CCP do not exceed those observed with plasma transfusion in general, it is reasonable to believe that the known and potential benefits of use of high titer CCP outweigh the known and potential risks when used for the treatment of hospitalized patients with COVID-19, particularly early in the course of illness or in patients with impaired humoral immunity. Results from ongoing RCTs are expected to continue inform the optimal patient populations and product characteristics for efficacy of CCP in COVID-19.

**Recommendation:** *The conditions of Emergency Use Authorization for CCP for the treatment of hospitalized patients with COVID-19 should be revised to exclude the use of low titer CCP. High titer CCP continues to meet criteria for Emergency Use Authorization for the treatment of hospitalized patients with COVID-19 early in the course of hospitalization.* The letter of authorization and accompanying fact sheets should be revised to emphasize early administration of CCP in the absence of immunodeficiency or immunosuppression. Additional results from adequate and well-controlled trials will continue to be evaluated to further characterize the patient populations and product characteristics meeting EUA criteria.

2021-02-04 Hinton DM: U.S. Food and Drug Administration Letter to Nikki Bratcher-Bowman, Acting Assistant Secretary for Preparedness and Response, EUA-update regarding COVID-19 Convalescent plasma. February 4, 2021. (Please note that the position of Assistant Secretary of Preparedness and Response changed from February 2, 2021 (48 hours previous) from Robert Kadlec, M.D. who had been appointed by President Trump to an Acting Assistant Secretary for Preparedness and Response under the Biden Administration: Nikki Bratcher-Bowman.) (Ref 740)  
<https://web.archive.org/web/20210218201225/https://www.fda.gov/media/141477/download>

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3), the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19 (the virus was later named SARS-CoV-2).<sup>1</sup> On March 27, 2020, on the basis of such determination, the Secretary of HHS declared that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic,

pursuant to Section 564 of the Act, subject to the terms of any authorization issued under that section.<sup>2</sup> On August 23, 2020, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the emergency use of COVID-19 convalescent plasma for the treatment of hospitalized patients with Coronavirus Disease 2019 (COVID-19), pursuant to Section 564 of the Act.<sup>3</sup> On November 30, 2020, FDA reissued the August 23, 2020, Letter of Authorization to add a test acceptable to be used in the manufacture of COVID-19 convalescent plasma.<sup>4</sup> Having concluded that revising this EUA is appropriate to protect the public health or safety under Section 564(g)(2)(C) of the Act (21 U.S.C. § 360bbb-3(g)(2)(C)), **FDA is again reissuing the Letter of Authorization in its entirety with revisions to:** (1) include updates based on data from additional clinical trials; **(2) clarify that the authorization is limited to use of only high titer COVID-19 convalescent plasma in hospitalized patients early in the course of disease and those hospitalized with impaired humoral immunity;** (3) add the Abbott SARS-CoV-2 IgG test (ARCHITECT and Alinity i platforms), Beckman Coulter Access SARS-CoV-2 IgG test, EUROIMMUN Anti-SARS-CoV-2 ELISA (IgG) test, GenScript cPass SARS-CoV-2 Neutralization Antibody Detection Kit test, Kantaro COVID-SeroKlir test, Roche Elecsys AntiSARS-CoV-2 S test, and Siemens ADVIA Centaur SARS-CoV-2 IgG (COV2G) test as acceptable tests to be used for the purpose of qualifying high titer COVID-19 convalescent plasma in the manufacture of COVID-19 convalescent plasma; and (4) change the cutoff of the Ortho VITROS Anti-SARS-CoV-2 IgG test from  $S/C \geq 12.0$  to  $S/C \geq 9.5$  for qualification of COVID-19 convalescent plasma as high titer. COVID-19 convalescent plasma is human plasma collected from individuals whose plasma contains anti-SARS-CoV-2 antibodies, and who meet all donor eligibility requirements (21 CFR 630.10 and 21 CFR 630.15) and qualifications. It is an investigational product and is not currently approved or licensed for any indication. The initial issuance of this EUA for COVID-19 convalescent plasma was based on review of historical evidence using convalescent plasma in prior outbreaks of respiratory viruses, certain preclinical evidence, results from small clinical trials of convalescent plasma conducted during the current outbreak, and data obtained from the National Convalescent Plasma Expanded Access Protocol (EAP) sponsored by the Mayo Clinic.<sup>5</sup> Following the August 23, 2020 authorization, additional studies, including randomized, controlled trials, have provided data to further inform the safety and efficacy of COVID-19 convalescent plasma, and further characterize product attributes and patient populations for its use. Based on assessment of these data, potential clinical benefit of transfusion of COVID-19 convalescent plasma in hospitalized patients with COVID-19 is associated with high titer units administered early in the course of disease.<sup>6</sup> Transfusion of COVID-19 convalescent plasma in hospitalized patients late in the course of illness (e.g., following respiratory failure requiring intubation and mechanical ventilation) has not been associated with clinical benefit. These considerations may be different in patients with suppressed or deficient humoral immunity. **Therefore, this EUA is being revised to authorize only the use of high titer COVID-19 convalescent plasma, for the treatment of hospitalized patients with COVID-19, early in the disease course.** The related fact sheets are revised accordingly. The use of low titer COVID-19 convalescent plasma is no longer authorized under this EUA.

**It is reasonable to believe that the known and potential benefits of high titer COVID-19 convalescent plasma outweigh its known and potential risks for the treatment of patients hospitalized with COVID-19 early in the disease course.**<sup>7</sup> COVID-19 convalescent plasma should not be considered a new standard of care for the treatment of patients with COVID-19. Given that the clinical evidence supporting this EUA remains limited, data from additional randomized, controlled trials are needed. Ongoing clinical trials of COVID-19 convalescent plasma should not be amended based on the issuance of this updated EUA; providers are encouraged to enroll patients in those trials. Having concluded that the criteria for issuance of this authorization under 564(c) of the Act are met, I am authorizing the emergency use of high titer COVID-19 convalescent plasma for treatment of hospitalized patients with COVID-19, as described in the Scope of

Authorization section of this letter (Section II) and subject to the terms of this authorization.

2021-02-04 U.S. Food & Drug Administration: FDA in Brief: FDA Updates Emergency Use Authorization for COVID-19 Convalescent Plasma to Reflect New Data, February 4, 2021. **This is deliberate legal obfuscation on the part of the FDA by stating that it was limiting authorization-- *de facto*, the FDA was really expanding authorization by appropriately limiting the EUA for COVID-19 Convalescent Plasma to "early in the disease course" which was contrary to FDA directives from March 24, 2020 to September 2, 2020 when the criteria was that CCP could *only* be given to severe patients late in the disease course. The provision of CCP late in the disease course was *de facto* perpetuated by the fact that the FDA had unobtrusively removed the strict severity of illness criteria late in the disease course from all FDA documentation by overwriting on September 2, 2020 and going forward on all subsequent documentation and not announcing it *officially* to the U.S. Medical and Research Community, probably the rest of the Federal Government, and most definitely not to the American people. The "high dose" vs "low dose" concern is a secondary issue—that was used as a distraction by the FDA—as with monoclonal antibodies/antibody cocktails, COVID-19 Convalescent Plasma and monoclonal antibodies **are all *Passive Immunization*** and are therapeutically identical if given **EARLY IN THE COURSE OF THE DISEASE.** <https://www.fda.gov/news-events/fda-brief/fda-brief-fda-updates-emergency-use-authorization-covid-19-convalescent-plasma-reflect-new-data> (Ref. 741)**

The following quote is attributed to **Peter Marks, M.D., Ph.D.,  
Director of FDA's Center for Biologics Evaluation and  
Research:**

"The FDA is issuing a revision of the Emergency Use Authorization (EUA) for COVID-19 convalescent plasma as a result of our evaluation of the most recent information available. Based upon data from new clinical trials analyzed or reported since the original EUA was issued in August 2020, **we have revised the EUA to limit the authorization to the use of high titer COVID-19 convalescent plasma for the treatment of hospitalized patients early in the disease course.** This and other changes to the EUA represent important updates to the use of convalescent plasma for the treatment of COVID-19 patients.

"Issuance of, and updates to, EUAs are based on a thorough evaluation of currently available scientific evidence about medical products. In this case, as additional scientific evidence about COVID-19 convalescent plasma emerged, we revised the EUA to reflect the updated evidence. COVID-19 convalescent plasma used according to the revised EUA may have efficacy and its known and potential benefits outweigh its known and potential risks."

2021-02-05 Dockser Marcus A: FDA Limits Use of Convalescent Plasma as Covid-19 Treatment. Agency to scale back authorization of the antibody-rich blood component after studies yielded mixed results. The Wall Street Journal Feb 5, 2021. (Ref 746). <https://www.wsj.com/articles/fda-limits-use-of-convalescent-plasma-as-covid-19-treatment-11612537239>

***[This article is copied verbatim from the Wall Street Journal with annotations so as to translate what is meaningfully being said by those interviewed!].***

The Food and Drug Administration [is scaling back its authorization](#) of the use of convalescent blood-plasma for Covid-19 patients in an effort to guide physicians who have faced a confusing thicket of data about the therapy's effectiveness.

The agency said late Thursday that the authorization, [a subject of controversy since it was first issued last August](#), would be revised to limit the use of plasma to **hospitalized patients *early in the course of the disease* and hospitalized patients with a medical condition that impairs their ability to make antibodies**. Patients will be allowed to receive **only plasma containing high concentrations of antibodies**.

"The update is meant so convalescent plasma can best be used on those who will benefit," said Peter Marks, director of the FDA's Center for Biologics Evaluation and Research. "It is being used somewhat more indiscriminately." ***[High-titer COVID-19 Convalescent Plasma should be given to everyone becoming COVID-19 positive within <72 hours. – NOT just those hospitalized.—C. Andrus]***

Dr. Claudia Cohn, chief medical officer of AABB, an organization representing the transfusion-medicine community, said the group plans to issue interim recommendations on convalescent plasma later this month. "There are so many studies coming out with different conclusions," she said. "It is not clean, it is not black and white."

Dr. Marks said the FDA reached its decision after evaluating results from several recent studies. Some showed benefits from convalescent plasma, the antibody-containing fluid derived from the blood of people who have recovered from Covid-19. Others showed no benefit.

Two clinical trials of convalescent plasma for hospitalized patients shut down last month after investigators said there appeared to be no benefit. Three trials involving hospitalized patients recently reported some benefit for the plasma, but only when given to patients soon after admission. **Still another trial showed that elderly outpatients given plasma shortly after showing symptoms were less likely to develop serious disease.** ----

***[This was the January 6, 2021 publication in The New England Journal of Medicine which is the ONLY Prospective randomized, placebo controlled trial of CCP administration in one cohesive age group (~70 years of age). THIS IS A LANDMARK STUDY! – C. Andrus]***

Arturo Casadevall, chair of molecular microbiology and immunology at the Johns Hopkins Bloomberg School of Public Health, called the FDA decision "a step forward."

He said, “Physicians in the U.S. for the first time are going to have guidance on when to use it and how to use” convalescent plasma.

Dr. Casadevall is a co-founder of the Covid-19 Convalescent Plasma Project, which helped [organize a nationwide expanded-access study of convalescent plasma](#) that began last April.

Despite the contradictory findings, convalescent plasma remains in demand—in part because there are few effective treatments for Covid-19 and many people remain unvaccinated. Since the FDA issued the emergency authorization last August, the blood industry has distributed on average about 20,600 units of convalescent plasma a week to hospitals around the country, according to the American Red Cross.

The FDA’s earlier decision to authorize [convalescent plasma for hospitalized Covid-19 patients](#) was based in large part on results from an agency-sponsored [expanded-access program](#), through which more than 72,000 patients received plasma. For a study published last month in the New England Journal of Medicine, researchers analyzed data from 3,000 of those patients and reported an apparent survival benefit among hospitalized patients not on mechanical ventilation who received plasma containing high concentrations of antibodies.

But many scientists expressed skepticism about that finding, saying expanded-access studies lack the scientific rigor of traditional trials because they have no control group to compare any apparent effect.

**The FDA’s Dr. Marks said the authorization of convalescent plasma “could have been handled much better. It had to do with the sense of urgency everyone is feeling. I can’t blame anyone for feeling a sense of urgency.” -- [As Dr. Marks is the Director of the FDA’s CBER (Center for Biologics Evaluation and Research), it was his sole responsibility to have handled it better from March 2020 to the present for the biologic: COVID-19 Convalescent Plasma which is a biosimilar biologic to rabies vaccine, gamma globulin, RhoGam, hypertet, small pox convalescent plasma, IVIG, FFP, etc., etc., etc!]**

Dr. Marks also said the data could be confusing. Each unit of convalescent plasma is unique, reflecting the immune response of the recovered patient who donated it. It took time to figure out the best way to measure the antibodies in a unit, he added.

The U.S. isn’t the only government trying to establish reliable guidelines on the use of convalescent plasma. In Argentina, a study in elderly outpatients published last month in the New England Journal of Medicine contributed to current recommendations there to treat elderly Covid-19 patients early in the course of their illness. “Plasma supplies are not endless, and invariably public health officials face difficult decisions,” said study co-author Dr. Fernando Polack of Fundación Infant in Buenos Aires. “In any of these decisions, guidelines based on data are necessary and are the best way for clinicians to feel comfortable when facing individual cases.”

**Louis M. Katz**, chief medical officer of Mississippi Valley Regional Blood Center in Davenport, Iowa, which provides blood products for over 120 hospitals, said the evidence supporting the use of convalescent plasma in hospitalized patients is weak. **“I think the**



data is there that it works early,” he said. “As you move into sicker and sicker people, the evidence gets thinner and thinner.”

In an editorial that accompanied the New England Journal of Medicine paper on the U.S. expanded-access study, Dr. Katz said convalescent plasma should be used only in patients early in the course of the disease. The problem with that suggestion, he later added, is the FDA emergency-use authorization still covers only hospitalized patients, who tend to show up at the hospital when they have been sick for a longer time. – *[This is the problem, to become hospitalized, most patients have to be very sick and thus outside the <72 hour window! – C. Andrus, M.D.]*

Treating Covid-19 patients who are just starting to show symptoms poses its own challenges. “Logistically, it is very difficult to treat patients earlier,” Dr. Katz said. “It’s hard to transfuse lots of plasma in outpatients.” ***[BUT IT CAN BE DOWN IN INFUSION CENTERS or Hospital outpatient centers as is done for all infusion chemotherapies, chronic blood transfusions, etc! – C. Andrus, M.D.]***

Dr. Marks said a large National Institutes of Health study is now under way to test convalescent plasma in people with Covid-19 who are sick enough to come to the emergency room but aren’t admitted to the hospital, as are other randomized controlled trials of plasma in outpatients. “Until we have those data, we are going to keep the authorization to hospitalized patients,” he said. “We will refine it again if appropriate. This is a scarce resource.” ***[High-titer COVID-19 Convalescent Plasma should NOT be a scarce resource as it can be obtained twice a week from the same convalescent donor by PLASMAPHORESIS and the product from each donation will yield 2 doses (4 doses per week) and it can be stored as FFP (Fresh Frozen Plasma) for at least a year! In short, there are over 5,000 blood banks in the US so if each Blood Bank processed 20 units a day of COVID-19 Convalescent Plasma, that would be:***

***20 donations / day times 7 days/week times >5000 U.S. Blood Banks times 2 doses of CCP / donation = greater than 1.4 million doses per week of CCP  
– C. Andrus, M.D.]***

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87990cbe856818d5eddac44c7b1cdeb8

*Appeared in the February 6, 2021, print edition as 'FDA Limits Plasma as Treatment.'*

2021-02-10 **Andrus C**: Use of COVID-19 convalescent plasma EARLY in the course of the disease. ResearchGate. (Ref 756).



[https://www.researchgate.net/post/Use\\_of\\_COVID-19\\_Convalescent\\_Plasma\\_EARLY\\_in\\_the\\_course\\_of\\_the\\_disease](https://www.researchgate.net/post/Use_of_COVID-19_Convalescent_Plasma_EARLY_in_the_course_of_the_disease)

2021-02-18 **Katz LM: (A Little) Clarity on convalescent plasma for Covid-19.** Initially published on January 13, 2021) This editorial was republished in the N Engl J Med, 2021 Feb 18; 384 (7): 666 – 668.

<https://www.nejm.org/doi/full/10.1056/NEJMe2035678> In the article, it was not disclosed that Dr. Katz is the Chief Medical Director, ImpactLife:  
<https://www.bloodcenter.org/about/news/authors/dr-louis-katz-a4/> (Ref 770)

[Please note that Dr. Katz was not fully identified by this paper. Dr. Katz is “...the former Chief Medical Officer at America’s Blood Centers in Washington, DC, an ABC past president, former board member and a past chair of its Scientific, Medical and Technical Committee. His transfusion medicine career has been dominated by attention to transfusion transmitted infections. He has served multiple terms as the chair of the AABB Transfusion Transmitted Diseases committee and served on many AABB committee and working groups. Dr. Katz is on the Editorial Board of the journal Transfusion, has served on the FDA Blood Products Advisory Committee as a member, industry representative and chair, and is a current member of the HHS Advisory Committee on Blood and Tissue Safety and Availability.” – Winn KI, Katz L, Goel R: Dr. Louis Katz, Acting Chief Medical Director. ImpactLife (formerly Mississippi Valley Regional Blood Center). <https://www.bloodcenter.org/about/news/authors/dr-louis-katz-a4/> ]

*The text of this article that follows is verbatim because it explains the mindset of those involved in the FDA’s, NIH’s, and The White House’s convoluted obfuscation in the lack of treatment during the viremic phase of those infected with COVID-19 with passive immunization (Covid-19 Convalescent Plasma [CCP]) AND THE COVER-UP by US Medicine and the US Government THAT HAS BEEN PERVASIVE OVER THE LAST 15 months. While advocating for the appropriate administration early in the viremic phase of Covid-19 (<72 hours from symptoms/diagnosis) in the outpatient setting and NOT IN THE HOSPITAL SETTING, this New England Journal of Medicine editorial fails strongly to emphasis the definitive utility of PASSIVE IMMUNIZATION and thus has been ignored by the medical community, the US federal government, and the US public-at-large. Even after the FDA quietly removed from all its official documentation on 9/2/2020 mandating the strict erroneous CCP administration criteria initiated by the FDA / vis-à-vis The White House on March 24, 2020 for use only in severely affected patients--late in the disease--administration of CCP (during the cytokine cascade and bradykinin phase which both are dominant in severely hospitalized patients and then only somewhat effective treatment is supportive) continued. The wrong-time administration of CCP became the de facto standard-of-care. The majority of 722,000 doses of CCP given over the last 15 months to individuals late in their disease course throughout the U.S.A. (and much of the World) was given at the WRONG TIME. –*

And the FDA, the NIH, the VA, *The White House*,  
the *New England Journal of Medicine*, etc.

*knew it!*

PASSIVE IMMUNOTHERAPY has been used since the late 19th century, and in 1901, the first Nobel Prize in Physiology or Medicine was awarded for serum therapy for patients with diphtheria. During the 1918 pandemic, serum from convalescent patients was used to treat influenza, with some apparent success.<sup>1</sup> Today, the use of immunoglobulins has been established for the prophylaxis and treatment of a variety of infections, including those with respiratory syncytial virus, cytomegalovirus, and

hepatitis B or hepatitis A virus. More recently, passive immunotherapy has been evaluated for severe acute respiratory syndrome (SARS), Middle East respiratory syndrome, and Ebola virus disease. Intravenous human immunoglobulin has revolutionized the management of immunoglobulin deficiency states.

The use of convalescent plasma against SARS coronavirus 2 (SARS-CoV-2) is advocated for the treatment of patients with coronavirus disease 2019 (Covid-19). The experience with influenza A is relevant, and a meta-analysis suggested that **early treatment, before critical illness develops**, may be an important **predictor of the efficacy of passive immunotherapy for that pathogen**.<sup>1</sup> The authors of that meta-analysis acknowledged the low quality of the available evidence regarding early treatment. Another meta-analysis of studies of convalescent plasma and hyperimmune immunoglobulin in patients with influenza A and SARS suggested a mortality benefit **“when convalescent plasma is administered early after symptom onset.”**<sup>2</sup> However, in a randomized, controlled trial, high-titer convalescent plasma from patients who had recovered from H1N1 influenza was ineffective against severe influenza A infection in hospitalized children and adults.<sup>3</sup>

**Initial randomized trials of convalescent plasma in patients with Covid-19 focused on hospitalized patients who were already moderately to severely ill**, and these trials provided weak evidence of clinical efficacy.<sup>4-6</sup> **Some were underpowered** when nonpharmaceutical interventions such as masking and social and physical distancing reduced the incidence of Covid-19 and enrollment was limited. Also, these trials were heterogeneous with respect to the characteristics of the convalescent plasma used (e.g., its antibody content and the stratification of the recipients according to their serologic status). **No unexpected safety signals beyond the recognized risks of plasma transfusion (i.e., fluid overload, transfusion-associated acute lung injury, and allergy) have emerged, nor has there been evidence of antibody-dependent enhancement of Covid-19 severity.** Accordingly, it is difficult to make actionable conclusions about the clinical value of convalescent plasma.

Observational studies have been more positive than randomized trials; some, but not all, of these studies have suggested modest clinical effects and measurable surrogate virologic outcomes.<sup>7,8</sup> They have confirmed the safety profile of plasma transfusions but have some of the same issues as randomized trials, in addition to the potential biases and shortcomings inherent in observational studies.

The Food and Drug Administration (FDA) argued that a “totality of the evidence” suggested that the benefits of convalescent plasma would outweigh its risks, and given the lack of effective treatments, **the FDA granted an Emergency Use Authorization (EUA) and provided guidance on the manufacture and use of convalescent plasma in hospitalized patients with signs of progressive infection.** By contrast, a National Institutes of Health guidelines panel stated that “the data are insufficient to recommend for or against” the use of convalescent plasma. The Infectious Diseases Society of America and the AABB (formerly known as the American Association of Blood Banks) recommend that the use of convalescent plasma be limited to clinical trials, that critically ill patients and **those in the intensive care unit (ICU) are unlikely to benefit from transfusions of convalescent plasma**, and that **convalescent plasma should be used as early as possible in the course of infection (preferably within 3 days after diagnosis) in order to achieve the best outcomes.**<sup>9</sup>

Considering the number of SARS-CoV-2 infections, the paucity of treatment options, and the enthusiasm for and controversy about convalescent plasma, a high-quality, multicenter, randomized, controlled trial is most welcome. **Libster and colleagues now report in the *Journal*<sup>10</sup> the results of a well-executed trial of early convalescent plasma in older adult patients in whom symptomatic SARS-CoV-2 infection was**

**diagnosed with the use of a polymerase-chain-reaction assay. In this double-blind trial, 250 ml of convalescent plasma with an IgG titer greater than 1:1000 against SARS-CoV-2 spike (S) protein was compared with saline placebo in patients who were 65 to 74 years of age and had prespecified coexisting conditions and in patients who were 75 years of age or older with or without coexisting conditions.**

The patients received convalescent plasma or placebo less than 72 hours after symptom onset. In the intention-to-treat population, a primary end-point event (progression to predefined severe disease during follow-up) occurred in 16% (13 of 80 patients) and 31% (25 of 80 patients) of the well-matched convalescent plasma and placebo groups, respectively. A dose-dependent effect relative to the antibody titers after infusion was observed, and this effect was larger after the exclusion of 6 patients who had a primary end-point event before infusion. The benefits of convalescent plasma with respect to the secondary end points were consistent with those associated with the primary end point. No serious adverse events were observed. **The authors conclude that “early administration of high-titer convalescent plasma against SARS-CoV-2 to mildly ill infected older adults reduced the progression of Covid-19.”** Even before the current trial, **the EUA emphasized the potential advantages of early therapy with high-titer convalescent plasma.** Unfortunately, a direct comparison of antibody levels in the current trial with assays specified in the FDA EUA is not available. Antibody titers in the recipients at enrollment were not provided, so no comment can be made about the usefulness of seroreactivity in patients as a criterion for convalescent plasma use. At this time, convalescent plasma should be reserved for patients in whom the duration, severity, and risk of progression of illness are similar to those in the patients in this trial. Younger high-risk patients (and certain immunodeficient patients) with these disease characteristics should be considered as well.

The supply of convalescent plasma has been tenuous during the marked increase in Covid-19 cases during the fall in the United States, although recent collections have improved. From September 28 through December 27, 2020, distributions of new and stockpiled units of convalescent plasma to hospitals in the United States exceeded collections by 7785 units (Block W: personal communication). **If collections are restricted to the high-antibody titers and patient indications described in the article by Libster et al., the supply of convalescent plasma will be stressed. At my center, high-titer collections (as defined by the FDA) account for only 19.5% of seroreactive convalescent plasma donations. Shifting the pool of potential recipients away from those included in the EUA to the many infected outpatients whose risk of hospitalization and eventual need for advanced care cannot be precisely estimated should lead to the extension of convalescent plasma transfusions to prehospital venues (although this is not yet permitted in the EUA).**

**Uncontrolled compassionate use of convalescent plasma in patients other than those with an early infection that is likely to progress to more severe illness should be discouraged,** even though clinicians recognize how difficult it can be to “just stand there” at the bedside of a patient in the ICU. Constraints on therapies for Covid-19 that are effective for limited patient populations are a powerful argument for continued consistent adherence to recommended nonpharmaceutical interventions and the rapid deployment and uptake of effective vaccines.

In an obfuscating way, Dr. Katz confirms that when high-dose COVID-19 Convalescent Plasma is given **EARLY**(<72 from time of onset or diagnosis) and is compared with placebo in age-matched patients ~70 years of age, progression to severe COVID-19 disease (e.g. pneumonitis, blood clots, etc.) is 16% versus 31%, respectively.

**THUS, COVID-19 CONVALESCENT PLASMA when given EARLY to an AGE COHESIVE GROUP in the VIREMIC PHASE OF COVID-19 (<72 HOURS) has a 50% DECREASED / OBSERVED REDUCTION IN PROGRESSION to the LATER MULTIORGAN-SYSTEM PHASE OF COVID-19 INVOLVING (1) THE CYTOKINE CASCADE STORM and (2) the ACCUMULATION OF DETRIMENTAL LEVELS OF BRADYKININ.**

2021-02-18 Whyte J: FDA revises EUA for COVID-19 Convalescent Plasma. WebMD. John Whyte, M.D., Chief Medical Officer at WebMD interviews Peter Marks, M.D., PhD, Director for the Center for Biologics Evaluation and Research at the U.S. FDA: FDA revises EUA for COVID-19 convalescent plasma. <https://www.webmd.com/coronavirus-in-context/video/peter-marks-plasma> (Ref 771)

*The following is a very important interview as Peter Marks, M.D., PhD as the Director for CBER at the FDA had the ability in March 2020 to have designated COVID-19 Convalescent Plasma a Biosimilar Biologic (like rabies vaccine, HyperTet, RhoGam, IVIG, etc.) and the designation of “Investigational” and all the Expanded Access / (compassionate use only) would have been avoided. This would have precluded the issuing of the eligibility criteria of March 24, 2020 which directed administration late in the course of the disease—THE WRONG TIME as is confirmed by Dr. Marks in the 2/18/2021 interview! Immediately following is from the March 24, 2021 FDA announcement. [https://notifylibrary.org/sites/default/files/Investigational%20COVID-19%20Convalescent%20Plasma%20-%20Emergency%20INDs%20\\_%20FDA.pdf](https://notifylibrary.org/sites/default/files/Investigational%20COVID-19%20Convalescent%20Plasma%20-%20Emergency%20INDs%20_%20FDA.pdf)*

The container label of COVID-19 convalescent plasma units must include the following statement, “Caution: New Drug--Limited by Federal (or United States) law to investigational use.” (21 CFR 312.6 (a))

- **Eligible patients for use under expanded access provisions:**
  - Must have laboratory confirmed COVID-19
  - Must have severe or immediately life-threatening COVID-19, for example:<sup>1</sup>
    - Severe disease is defined as:
      - dyspnea,
      - respiratory frequency  $\geq 30/\text{min}$ ,
      - blood oxygen saturation  $\leq 93\%$ ,
      - partial pressure of arterial oxygen to fraction of inspired oxygen ratio  $< 300$ , and/or
      - lung infiltrates  $> 50\%$  within 24 to 48 hours
    - Life-threatening disease is defined as:
      - respiratory failure,
      - septic shock, and/or

<https://www.fda.gov/vaccines-blood-biologics/investigational-new-drug-ind-or-device-exemption-ide-process-cber/investigational-covid-19-convale...> 2/3

27/3/2020

Investigational COVID-19 Convalescent Plasma - Emergency INDs | FDA

- multiple organ dysfunction or failure
- Must provide informed consent

*In addition to the above, FDA is continuing to work with its government partners including the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC) to develop master protocols for use by multiple investigators in order to coordinate the collection and use of COVID-19 convalescent plasma.*

<sup>1</sup>Wu Z, McGoogan JM. Characteristics of and Important Lessons From the Coronavirus Disease 2019 (COVID-19) Outbreak in China: Summary of a Report of 72 314 Cases From the Chinese Center for Disease Control and Prevention. *JAMA*. Published online February 24, 2020. doi:10.1001/jama.2020.2648

## Start of the interview of Dr. Marks by Dr. Whyte:

JOHN WHYTE: Welcome, everyone. You're watching "Coronavirus in Context." I'm Dr. John Whyte, chief medical officer at WebMD. We're spending a lot of time talking about vaccines. But we can't forget about the role of therapeutics for those persons who have caught COVID and are having a serious case. And there's been some recent changes in when and how we should use convalescent plasma.

So to help explain these changes, I've asked Dr. Peter Marks. He's the director for the Center for Biologics Evaluation and Research at the US Food and Drug Administration. Welcome back, Dr. Marks.

PETER MARKS: Thanks very much for having me.

JOHN WHYTE: Let's just take a minute and remind our audience-- we have a lot of folks from Medscape, but also consumers-- what is convalescent plasma?

**PETER MARKS:** So convalescent plasma is the blood plasma that's taken from an individual who has been infected with COVID-19 and who's recovered from the infection. In some cases, they might not even have known they had the infection, but they obviously did. And they might have antibodies that have been detected and told they had COVID-19, or they might have had a PCR test when they were sick with COVID, were told they had COVID-19, and afterwards, after they recover and they're fully recovered, they're eligible to potentially donate convalescent plasma, which is usually taken by plasmapheresis. People are put on a machine for about an hour, and the blood products taken out. And the blood cells are given back to the person. The plasma is taken off.

JOHN WHYTE: Now, the FDA authorized the use, under an emergency use authorization, of convalescent plasma in August of last year. And recently, you revised that authorization-- actually, in many ways made it more restrictive. Let's go over what the change in the EUA is.

PETER MARKS: Right. So the emergency use authorization that was issued in August was a very broad emergency use authorization, because at that time we were relying on the evidence at the time which said that it appeared that convalescent plasma could potentially benefit a broad swath of people. And we weren't really sure who it might benefit the absolute most. We knew it was best when given in high titer, and we knew that it seemed to be best in people who were treated earlier. But we couldn't rule out that it was having some benefit to people later on in the course of disease.

JOHN WHYTE: And at that time, they didn't have to be hospitalized.

**PETER MARKS:** We always required that the patients be hospitalized. It was always hospitalized patients. And what happened, then, is over the course of the past few months-- we follow the literature very closely-- there have been studies that have come out of various places. Some have been negative for convalescent plasma-- they said that it's not had a beneficial effect. Others have been quite positive.

And over the course of time, we've looked closely at them, and we sorted them out. And it became pretty clear that when people were treated early on with high-titer convalescent plasma, they seemed to be showing some benefit. And when you treat late, you just don't see that benefit. Particularly when you treat people who have been on a ventilator, it just-- with the rare exception of people who have defects in immunity, people who have diseases like hematologic malignancies like chronic lymphocytic leukemia-- those people, they may benefit late on, because they don't make antibodies.

But for the large majority of people who have normal immune systems, if you treat late, convalescent plasma is not seeming to benefit, whereas if you treat early, within the first few days after diagnosis, the data are increasingly supporting that there is some benefit there. It's not a massive benefit. It's a modest benefit.

JOHN WHYTE: How would you articulate that benefit?

**PETER MARKS:** I can cite the data that we have from roughly 20,000 individuals who received 1 unit of convalescent plasma. Roughly half of those people got high



titer and half of them got low titer of various levels. And the people who got the higher-titer plasma had about a 2-percent absolute reduction in mortality at seven days, which translates into about a 15-percent relative reduction if they were not intubated.

If they were intubated, they were on a ventilator, then there really wasn't any benefit. So those data really helped push us along towards saying it was time to kind of narrow down the emergency use authorization to say, look, don't use this late in people who are intubated-- that is, on a ventilator. Use it early on or earlier on in the course of disease.

Now, your next question might be, why not just use it as an outpatient? Hum. And the answer is--

JOHN WHYTE: Now you're interviewing yourself.

PETER MARKS: Nah. I might as well do that. I've done this enough. But the reason why we're not there yet is because we're waiting for some very well-designed studies that are being conducted, one by the National Heart, Lung, and Blood Institute, which will give us a good answer about the potential benefit in that setting.

JOHN WHYTE: Well, that's why I was asking you about hospitalized patients. Because if we talk about-- you mentioned it has to be used early on in the disease-- but what about severity of disease? Because many patients that aren't coming to the hospital until they're much further along-- so how do you do it, in the sense you want to do it early on, within those first couple of days, but sometimes we're telling patients not to come to the hospital or to the ER. So how do we balance that? So what's the severity of disease?

PETER MARKS: I think right now the way we balance it is we say that if you're somebody who's got early disease and you're interested, get onto the [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov) and find one of the sites around you that might be doing outpatient clinical trials with convalescent plasma. There are a number of sites doing that.

But I think, otherwise, when people are admitted to the hospital, it's probably a good thing for physicians to think right away, is this somebody for whom convalescent plasma may make sense? Again, if someone's intubated in that first couple days, maybe not. On the other hand, if someone needs supplemental oxygen, those patients did seem to benefit.

JOHN WHYTE: Now, let's talk about the person's underlying immune response, their humoral immunity. So who are those patients? Many patients are often asking about, what if they're immunocompromised? What do they qualify for? Talk to our listeners about what's that patient population-- because that's a component, their underlying immunity function.

PETER MARKS: So it's a great question. And we've actually kept up with the case reports that have been coming out. They're not trials, but they're a case series that have come out from around the globe, and it's very convergent. If you treat people who don't make a sufficient amount of antibody, either because they have a primary immunodeficiency syndrome or because they have [INAUDIBLE] cancer, and they can't make them, if you treat them, even if you seem to treat those people late, they seem to have benefit.

And there are some amazing case reports-- obviously, it's always N-of-1-- case

reports, you always have to take with a grain of salt-- but where people even very late on have had very good responses clearing viremia. So that kind of makes sense, right? Because if you're not able-- what we think, at least, that the antibodies are doing here-- the antibodies in convalescent plasma are acting like an antiviral, right? And if you give it early, they're acting like an antiviral would early on in getting things under control. Later on in the course of disease, where there are other organ damage effects, that's not the best time for an antiviral. And for those who are immunocompromised, it may be that they just have ongoing viremia, and you need to clear it. And giving them convalescent plasma helps take care of that.

JOHN WHYTE: One question we have gotten asked, Dr. Marks, is for those patients who have been fully immunized, are they able to donate plasma?

PETER MARKS: So it's a great question. And it's one we're still debating. Right now, if people have not had COVID-19 and get immunized-- so they're people who are COVID-19-negative to start, then get immunized-- we're not considering them as convalescent plasma donors, because they're making antibodies against just the S protein that are in the current generation of mRNA vaccines that are authorized.

We don't know, in terms of the convalescent plasma response that we're seeing, how much of the benefit is from the S-protein antibodies versus N-protein antibodies or other antibodies that are there. And until we have a little better idea on that, we're a little hesitant to swing over to have vaccinated individuals donate.

But this is an absolutely great question, because we're very much looking into this now. It would be nice to understand, because soon we're going to have a large population of people who will be fully vaccinated, probably with high titers of S antibodies, and it would be nice to know this. So stay tuned. We do that for other infectious diseases, and maybe we'll see it coming for COVID-19 soon enough.

JOHN WHYTE: Tell us how staff are doing. You had your general work that you had to do, in terms of vaccines, other biologics. Now you have the whole issue of COVID. How is everyone managing it?

PETER MARKS: Well, I have to say, we are incredibly lucky at FDA. We have a staff that has risen to the occasion in an amazing way. They're keeping the normal freight moving. And while they're keeping the normal freight moving, they are taking care of the avalanche of COVID-19-related applications.

Now, in some areas, there are a little lower number of applications than in others. But if you look, for instance, in the vaccine area, there is an avalanche there. And they're doing an incredible job keeping up. Same thing with, actually, some of the cellular therapies that have come in, and even the antibody therapies, et cetera. There are lots of them, right?

Our folks have done just an incredible job pitching in. People who have a little less work pitch in to those who are almost getting underwater in work. So it's been really wonderful. It has taken its toll. People are getting a little tired. And we're trying to make sure that we take care of people. But we're very lucky that people have really had such commitment to public health.

JOHN WHYTE: Absolutely. And then finally, all these emergency

use authorizations that are happening across the agency-- do you expect sponsors to apply for full licensure in a few months?

PETER MARKS: Yeah. So I-- for the vaccine sponsors in particular, we've told them that if they want to come in for an EUA, they should expect-- it's actually in our guidance-- they should expect that they're going to come in for a biologics license application. And so that's why the work isn't going to end soon, because as we're now dealing with some of the emergency use authorizations where the vaccines are becoming more mature, they've been in use for a little bit, I would suspect in the not-too-distant future we may see their biologics license applications. And so there will be kind of a cohort that will come along of license applications in the coming months.

JOHN WHYTE: Well, Dr. Marks, I want to thank you for taking the time, the work that you and all the staff at the Center for Biologics Evaluation and Research and all of FDA are doing to keep us all safe.

PETER MARKS: Thanks so much for having me today.

JOHN WHYTE: And if you have any questions about COVID, drop me a line. You can email us at [drjohn@webmd.net](mailto:drjohn@webmd.net) as well as post it on Facebook, Twitter, and Instagram. Thanks for watching.

2021-03-02 NIH halts trial of COVID-19 convalescent plasma in emergency department patients with mild symptoms – Study shows the treatment safe, but provides no significant benefit in this group. U.S. National Institute of Health announcement is: (Ref 785). <https://www.nih.gov/news-events/news-releases/nih-halts-trial-covid-19-convalescent-plasma-emergency-department-patients-mild-symptoms>

The actual clinic trial, *Convalescent Plasma in Outpatients with COVID-19 (SIREN C3PO)* NCT04355767, was: <https://clinicaltrials.gov/ct2/show/NCT04355767?term=NCT04355767&draw=2&rank=1>

There are no reported results on the ClinicalTrials website of which the NIH is making its decision to halt the trial. The trial was underpowered where there was no stratification by age and the study was discontinued with recruitment of only half the number of planned patients. This study was run by: SIREN, Strategies to Innovate emeRgENcy Care Clinical Trials, <https://clic-ctsa.org/node/9426>.

### NIH Announcement to discontinue the trial on March 2, 2021:

Launched in August 2020, the Clinical Trial of COVID-19 Convalescent Plasma of Outpatients (C3PO(link is external)) was being conducted at 47 hospital emergency departments across the United States and had enrolled 511 of the 900 participant recruitment goal. It was specifically looking at the effectiveness of COVID-19 convalescent plasma – blood plasma derived from patients who have recovered from COVID-19 – in adults who came to an emergency department with mild to moderate symptoms they had for a week or less. These patients also had at least one risk factor

associated with severe COVID-19, such as obesity, hypertension, diabetes, heart disease, or chronic lung disease, but none were ill enough at the time to be hospitalized.

(C3PO(link is external) <https://siren.network/clinical-trials/c3po>

## C3PO Clinical Trial of COVID-19 Convalescent Plasma of Outpatients

Registered with ClinicalTrials.gov: [NCT04355767](https://clinicaltrials.gov/ct2/show/NCT04355767?term=NCT04355767&draw=2&rank=1)

{  
<https://clinicaltrials.gov/ct2/show/NCT04355767?term=NCT04355767&draw=2&rank=1>

This is a registered NIH ClinicalTrials.gov

Award Number: 1OT2HL156812-01

**Status:** No new randomizations as of February 25, 2021.

[NIH Press Release \(March 2, 2021\)](#)

- Media inquiries: Refer to [Lenora Johnson, DrPH, MPH](#) and [Mark Sampson](#), and to this press release.

The Clinical Trial of COVID-19 Convalescent Plasma in Outpatients (C3PO) is a multi-center randomized, single blind, two arm, placebo controlled phase III trial with blinded outcome assessment to establish the safety and efficacy of a single dose of convalescent plasma (CP) for preventing the progression from mild to severe COVID-19 illness.

COVID-19 is a respiratory illness caused by the *Severe Acute Respiratory Syndrome Coronavirus 2* (SARS-CoV-2). As of May 1, 2020, over 3 million persons worldwide have been diagnosed with COVID-19 and approximately 250,000 persons have died from this disease. The majority (80%) of cases are categorized as mild, while approximately 15-20% of cases are categorized as severe, with about 5% of all cases progressing into critical illness, characterized by hypoxemic respiratory failure, shock, and end-organ failure. Among the 5% who develop severe disease, as many as 50% die. At present there is no specific therapy for preventing the progression of COVID-19 from mild to severe disease.

Passive antibody therapy using plasma from donors who have been infected and then recovered (convalescent plasma, CP) contains neutralizing antibodies against the infectious agent. Specifically, CP has been used in different respiratory illness epidemics, including the 1918 influenza pandemic, the 2003 SARS-CoV-1 outbreak, and the 2009 H1N1 influenza pandemic. Use of CP for emerging infections has persisted because of strong mechanistic and observational data, but efficacy has yet to be well tested or demonstrated in clinical trials. At this moment, there is no high quality evidence to support the efficacy of CP for treating COVID-19 illness. Conceptually, CP has the highest chance of showing efficacy if used for early treatment of patients at the highest risk for severe disease and mortality.

The overarching goal of this trial is to confirm or refute the role of passive immunization as a safe and efficacious therapy in preventing the progression from mild to severe/critical COVID-19 illness and to understand the

immunologic kinetics of anti-SARS-CoV-2 antibodies after passive immunization.

For more information on C3PO and convalescent plasma go to our [In the News page](https://siren.network/clinical-trials/c3po/in-the-news). (<https://siren.network/clinical-trials/c3po/in-the-news> )

## C3PO IN THE NEWS

### March 10, 2021

- Convalescent Plasma Strikes Out As COVID-19 Treatment  
<https://www.npr.org/975365309>

### October 22, 2020

- OHSU reserchers say they're having trouble recruiting patients for COVID-19 convalescent plasma trial  
[https://www.kptv.com/ohsu-researchers-say-theyre-having-trouble-recruiting-patients-for-covid-19-convalescent-plasma-trial/video\\_767f3558-10aa-5201-ad47-94322b60070d.html?block\\_id=988363](https://www.kptv.com/ohsu-researchers-say-theyre-having-trouble-recruiting-patients-for-covid-19-convalescent-plasma-trial/video_767f3558-10aa-5201-ad47-94322b60070d.html?block_id=988363)

### September 8, 2020

- NIH clinical trial explores use of convalescent plasma in at-risk outpatients with early COVID-19  
<https://www.nhlbi.nih.gov/news/2020/nih-clinical-trial-explores-use-convalescent-plasma-risk-outpatients-early-covid-19>

### August 25, 2020

- UF Health enrolls first patients in national COVID-19 study on convalescent blood plasma  
<https://m.ufhealth.org/news/2020/uf-health-enrolls-first-patients-national-covid-19-study-convalescent-blood-plasma>

### August 19, 2020

- New clinical trial at OHSU tests donated antibodies  
<https://news.ohsu.edu/2020/08/18/new-clinical-trial-at-ohsu-tests-donated-antibodies>

### August 6, 2020

- Will COVID-19 finally provide an answer on convalescent plasma?  
<https://www.medpagetoday.com/infectiousdisease/covid19/87936>

### August 3, 2020

- UM and Other Michigan hospitals to treat COVID-19 patients with convalescent plasm.  
<https://www.michiganradio.org/post/um-and-other-michigan-hospitals-treat-covid-19-patients-convalescent-plasma>

### July 30, 2020

- Michigan hospitals test if plasma from recovering patients can curb COVID-19  
<https://www.bridgemi.com/michigan-health-watch/michigan-hospitals-test-if-plasma-recovering-patients-can-curb-covid-19>
- Researchers at the University of Michigan's Michigan Medicine and three other medical centers were awarded a total of \$7 million from the National Heart, Lung, and Blood Institute (NHBLI) to study convalescent plasma in reducing symptoms of COVID-19 in patients with mild cases, Michigan Medicine announced Thursday.

<https://www.clickondetroit.com/video/health/2020/07/30/michigan-medicine-7-million-in-funding-for-covid-19-therapy-trial/>

- Michigan Medicine and three other medical centers receive \$7 million COVID-19 outpatient convalescent plasma therapy trial

[https://www.uofmhealth.org/news/archive/202007/michigan-medicine-and-three-other-medical-centers-receive-7?fbclid=IwAR2Rr1QbiOj6OxC0dcbv2Hw0Cn6uMlnx0BTz-buGJCf4SozAqutNDa6\\_1qo](https://www.uofmhealth.org/news/archive/202007/michigan-medicine-and-three-other-medical-centers-receive-7?fbclid=IwAR2Rr1QbiOj6OxC0dcbv2Hw0Cn6uMlnx0BTz-buGJCf4SozAqutNDa6_1qo)

- Trump urges people who have recovered from COVID-19 to donate blood plasma

<https://www.washingtonpost.com/health/2020/07/30/trump-urges-people-who-have-recovered-covid-19-donate-plasma/>

<https://www.c-span.org/video/?474383-1/president-trump-roundtable-discussion-donating-plasma>

#### July 29, 2020

- UPMC studying whether convalescent plasma help coronavirus patients with mild symptoms

<https://pittsburgh.cbslocal.com/2020/07/29/coronavirus-study-convalescent-plasma/>

- COVID-19 trial to study convalescent plasma in outpatient setting

<https://web.musc.edu/about/news-center/2020/07/29/covid19-trial-to-study-convalescent-plasma-in-outpatient-setting>

#### March 10, 2021

- Convalescent Plasma Strikes Out As COVID-19 Treatment

<https://www.npr.org/975365309>

2021-03-10 Harris R: Convalescent plasma strikes out as COVID-19 Treatment. NPR, March 10, 2021, 5:01 AM ET

More than half a million Americans have received an experimental treatment for COVID-19 called convalescent plasma. But a year into the pandemic, it's not clear who, if anyone, benefits from it.

That uncertainty highlights the challenges scientists have faced in their attempts to evaluate COVID-19 drugs.

On paper, treatment with convalescent plasma makes good sense. The idea is to take blood plasma from people who have recovered from COVID-19 and infuse it into patients with active infections. The antibodies in the donated plasma, in theory, would help fight the virus.

Based on that idea, last March [Dr. Nicole Bouvier](#) at the Icahn School of Medicine at Mount Sinai Hospital in New York decided to give it a try.

She recalls thinking, "we have this new disease that didn't have any known therapies, and convalescent plasma has been used in new epidemic and pandemic diseases," as recently as in an Ebola outbreak in West Africa a few years ago.

She says she was the first doctor to get special permission from the Food and Drug Administration to use it as an experimental treatment.

It was a huge commitment to line up people willing to donate plasma as well as to treat patients themselves, "so it was a big production," she says. "We ultimately screened over 70,000 people" and identified around 20,000 who had high antibody levels in their blood plasma.



Mount Sinai treated more than 1,400 patients, including throughout the height of New York City's nightmarish COVID-19 outbreak last spring. But all the while Bouvier had no idea whether the plasma really worked.

Finally, a couple of weeks ago, she had seen enough data from carefully controlled studies — and decided to stop offering the treatment.

"The straw that broke the camel's back was two very large cohort trials," she says. The [RECOVERY Trial](#) in the United Kingdom had studied more than 10,000 volunteers and found no benefit. Another one called [CONCOR-1](#), run by Canadians, had studied nearly 1,000 patients. It, too, stopped recruiting new patients because doing so would have been futile.

But those studies focused on people sick enough to be in the hospital. [Dr. Arturo Casadevall](#) at the Johns Hopkins Bloomberg School of Public Health is one of the prime advocates for convalescent plasma. He says he thinks the treatment needs to be done sooner, in the outpatient setting.

"From the very beginning here at Hopkins we set out to do outpatient trials," he says. "The trials were set up in March [of 2020], however it took many months to get the money to do it." With taxpayer money nowhere to be found, the study ultimately went forward with funding from the billionaire Michael Bloomberg, Casadevall says. A year later, the study at Hopkins still doesn't have results. And it's not just a question of funding. The entire U.S. medical research system isn't set up to do what's needed to identify new treatments during a pandemic.

[Dr. Derek Angus](#), chair of critical care medicine at the University of Pittsburgh, says that in a public health emergency scientists should be able to evaluate new treatments at hundreds of hospitals, in a matter of months.

"People might roll their eyes and say that's impossible, but that's largely what the United Kingdom has done," Angus says. "For all our capacity in the United States, it's depressing that we can't do a U.S. version."

The U.K. was able to launch its vast study quickly because Britain has a national health system that not only provides treatment but can conduct research. Research in the U.S. is balkanized among universities, drug companies and funders.

"We pride ourselves on having a very federated, independent system," Angus says. "But, gosh, that is very hard to turn on a dime to solve national problems."

To give just one example, a [national network of emergency room physicians](#) got federal funding to treat people with convalescent plasma, in a study named C3PO. Their patients were sick enough to show up in the emergency room, but well enough to go home afterward.

"We should have been able to get this done as quickly as they did in the U.K.," says [Dr. Kevin Schulman](#) at Stanford University. "It was just a much slower process to set up."

Schulman at Stanford was responsible for some of the logistics. And they were a nightmare, he says.

"I said tongue in cheek at some point when we had five patients in our study that we had at least 500 people touch a paper for the five patients we had recruited. And that's the opposite in the UK."

"Some of the contracts for the trial we are still negotiating even today," he adds. "You know, the U.K. didn't have any of that."

The C3PO study recently stopped recruiting patients. It had enrolled about 500 out of a planned 900, but an independent monitoring board concluded that continuing would have been futile.

This further casts doubt on the value of convalescent plasma.

"I don't see any point in offering plasma outside a clinical trial," says Angus from Pitt.

Several trials are ongoing. And there's still a chance that some of them could identify a group of patients, treated at a particular time with a particular concentration of plasma, who would benefit. So Bouvier at Mount Sinai hasn't given up on it completely.

In retrospect, it's understandable why convalescent plasma doesn't help people hospitalized with significant illness, she says. Serious illness is caused primarily by the body's reaction. Respiratory viruses like these don't persist for long. "They're sort of like, 'wham, bam, thank you, ma'am.' And then they're gone," Bouvier says.

"If a study comes along that identifies a population in whom convalescent plasma is useful, we will use it in that population" she says.

And if it does appear to be helpful for people who are early in the course of disease, that raises another question: Would plasma be better than the monoclonal antibody drugs already authorized by the Food and Drug Administration for that purpose and easier to use?

Casadevall at Hopkins argues that plasma might be better, especially if new virus variants can evade the antibody drugs. Antibodies in the plasma of people who have recovered have apparently been successful in controlling whatever virus they encountered, so the treatment actually evolves along with the pandemic.

But to figure out whether convalescent plasma is better than monoclonal antibodies could require another large, time-consuming study in a research system not set up to be nimble.

*You can contact NPR Science correspondent Richard Harris at [rharris@npr.org](mailto:rharris@npr.org).*

**Mr. President,** in the article that follows, the NIH, the FDA, and *The New England Journal of Medicine* published the “results from the C3PO SIREN trial” that the FDA used to withdraw its support of COVID-19 Convalescent Plasma on March 2, 2021. **This study is a skewed, underpowered trial which the NIH and the editors of *The New England Journal of Medicine* should never have published.**

2021-11-18 Korley FK, Durkalski-Mauldin V, Yeatts SD, Davenport RD, Dumont LJ, El Kassir N, Foster LD, Hah JM, Jaiswall S, Kaplan A, Lowell E, Mcdyer JF, Quinn J, Triulzi DJ, Van Huysen C, Stevenson VLM, Yadav K, Jones CW, Kea B, Burnett A, Reynolds JC, Greineder CF, Haas NL, Beiser DG, Silbergleit R, Barsa W, Callaway CW, for the SIREN-C3PO Investigators: Early convalescent plasma for high-risk outpatients with Covid-19. *N Engl J Med* 2021 Nov 18; 385 (21): 1951-1960. [SIREN-C3PO ClinicalTrials.gov number, NCT04355767.] (Ref 1022).  
<https://www.nejm.org/doi/pdf/10.1056/NEJMoa2103784?articleTools=true>

The Food and Drug Administration (FDA) approved an Investigational New Drug application for the trial. A central institutional review board (Advarra) reviewed and approved the trial protocol for all participating sites. (Advarra is a propriety company which on their internet listing are: Industry Experts—The Advarra Advantage: Our Expertise:

The Advarra advantage is built on our industry and domain expertise. Our experts are change agents and thought leaders with deep experience in clinical research. Together, we solve mission-critical challenges and bring life-changing therapies to participants faster. (Please note, Advarra's experts listed on their

website <https://www.advarra.com/about/industry-experts/> include **NO MEDICAL CLINICIANS LIKE AN M.D. OR A D.O.** In short, the SIREN-C3PO clinical trial NCT04355767 was reviewed by a proprietary company and **NOT** by any University School of Medicine IRB, any participating Hospital IRB, or the FDA's IRB directly.)

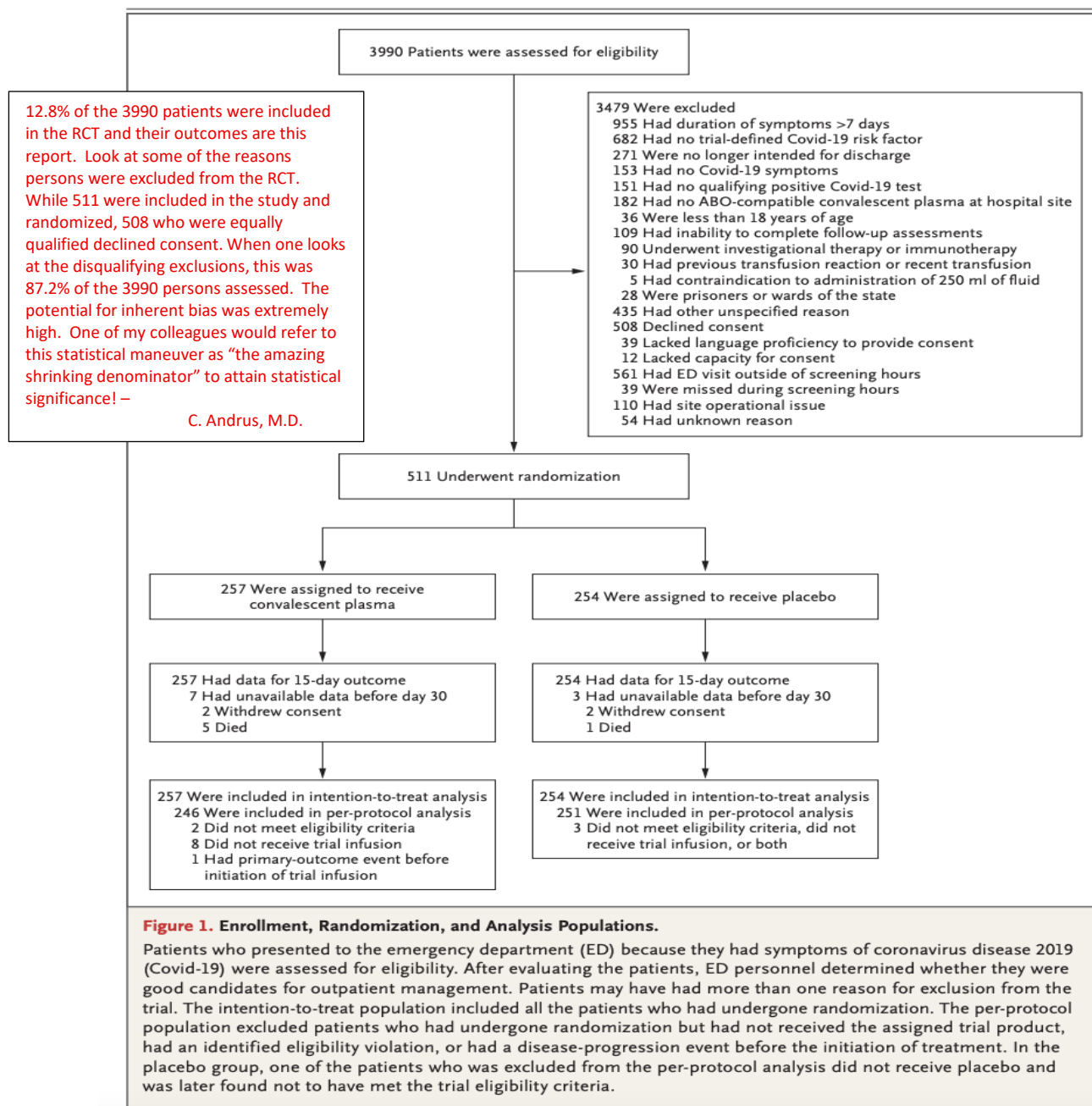
PLEASE note that the complete article and the supplementary appendix can be found:

Korley FK, Durkalski-Maudin V, Yeatts SD, Schulman K, Davenport RD, Dumont LJ, El Kassab N, Foster LD, Hah JM, Jaiswal S, Kaplan A, Lowell E, et al., for the DIREN-C3PO Investigators\*: Early convalescent plasma for high-risk outpatients with Covid-19. URL from article N Engl J Med 2021 Nov 18; 385: 1951-1960.

<https://www.nejm.org/doi/10.1056/NEJMoa2103784> This reference from the article is just an abbreviation; The full article is

<https://www.nejm.org/doi/pdf/10.1056/NEJMoa2103784?articleTools=true> and the Supplementary Appendix which is very important can be found at

([https://www.nejm.org/doi/suppl/10.1056/NEJMoa2103784/suppl\\_file/nejm2103784\\_appendix.pdf](https://www.nejm.org/doi/suppl/10.1056/NEJMoa2103784/suppl_file/nejm2103784_appendix.pdf)).



In Figure 1. **Enrollment, Randomization, and Analysis Populations**, of the 3990 patients presenting to the Emergency Room, 3479 (87.2%) were excluded as listed in the box above. The number of eligible patients that refused to participate in this placebo RCT was 508 and with the 561 that presented outside of ED screening hours and thus were rejected. These two exclusion factors totaled over twice as many patients (1069) as were included in this study of 511. What is more, when the NIH announced the closure of this trial on March 2, 2021 never reaching its statistical-directed goal of 900 patients (minimum  $\beta$

that the researchers agreed upon for a valid study), it proceeded to conclude that early administration of Passive Immunization via COVID-19 Convalescent Plasma (CCP) was not helpful. By excluding so many individuals, this study is probably a skewed, underpowered trial which the NIH and the editors of *The New England Journal of Medicine* should never have published.

It should also be noted that at the end of the author list on the front page of this article, it is stated: ...for the SIREN-C3PO Investigators\* where the “\*” refers to the statement in the right margin:

\*A list of the SIREN-C3PO investigators is provided in the Supplementary Appendix, available at NEJM.org which is 20 pages long ([https://www.nejm.org/doi/suppl/10.1056/NEJMoa2103784/suppl\\_file/nejmoa2103784\\_appendix.pdf](https://www.nejm.org/doi/suppl/10.1056/NEJMoa2103784/suppl_file/nejmoa2103784_appendix.pdf)) In this Supplementary Appendix major criteria for inclusion in the study changed from Protocol Version 1 of June 17, 2020 through Version 2 of July 2, 2020, Version 3 of September 7, 2020, Version 4 of November 3, 2020 to Version 5, February 16, 2021:

Has at least one study defined risk factor for severe COVID-19 illness:

Age  $\geq$  50 years; hypertension; diabetes; coronary artery disease; chronic lung disease; chronic kidney disease; immunosuppression

Yet, in Table 1. **Characteristics of the Patients at Baseline:**

Characteristic	Convalescent Plasma (N=257)	Placebo (N=254)
Median age (IQR)	54 (42-62)	54 (40-62)

there were patients of 42-49 years in the Convalescent Plasma group and patients of 40-49 years in the placebo group. Those patients should have been excluded due to their “youngness” that violated the stated inclusion criteria of all five Protocol versions of this trial. Were the SIREN-C3PO investigators, the NIH, and the editors of *The New England Journal of Medicine* being truthful to the American public? Has this paper done a disservice to the American public and to the World? As the NEJM attests to the participation in the *International Committee of Medical Journal Editors (ICMJE)*, they owe the American people an independent (independent from the U.S. Government and *The New England Journal of Medicine*) peer review of this paper with regards to appropriateness: Simply put, can this paper even conclude that which it concludes?

## CURRICULUM VITAE

Charles H. Andrus, M.D., F.A.C.S.

### A. Personal Information:

Home address	150 Emerald Green Court Creve Coeur, MO 63141 (314) 455-9482
Marital status	Married
Birth Date	March 28, 1953
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### B. Education:

#### *Undergraduate degree and major*

University of San Francisco, 1971-1975  
San Francisco, CA 94117  
BS in Chemistry (Amer. Chemical Soc. approved degree) summa cum laude

Cal State University at San Francisco, 1972-73 (summers)  
1600 Holloway Ave.  
San Francisco, CA 94132  
General Zoology and General Botany

#### *Graduate degree and major*

Saint Louis University School of Medicine, 1975-79  
1402 South Grand Blvd.  
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M.D. conferred May 12, 1979

#### *Postgraduate training*

Saint Louis University - Pediatrics, 1979-81  
Cardinal Glennon Memorial Hospital for Children  
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Saint Louis University - General Surgery, 1981-86  
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ABS Board Certification - Feb. 25, 1987



Surgical Endoscopy, 1987  
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**C. Board certification and Licensure:**

Passed National Boards:

1977	Part I	(6/77)	
1978	Part II	(9/78)	
1980	Part III	(3/80)	
	certified	07/01/80	No. 216934

American Board of Surgery

Identification #042223	
Certification	No. 32104
Recertified	2/25/1987
Recertified	1994 until July 1, 2007
Recertified	2006 until July 1, 2017
MOC (Maintenance of Certification) update	2014 until December 31, 2027
	12/2012 and then
	recertification 2014
NPI	1689611840
UPIN	No. 12496

**Expiration Date**

9/19/1980	Missouri State R8A85	1/31/2022
1996	Illinois 036-093146	7/31/2023
11/7/2001	California G86301	3/31/2023
1980	DEA number	6/30/2022
2/29/2005	Missouri BNDD	2/28/2022
4/9/2004	ATLS ID 84101 Instructor	10/28/2018
10/2005	BLS—Healthcare Provider	08/31/2022
April 2009	ACLS Provider	09/30/2022
June 2006	PALS Provider	
	PALS Instructor	
	ID#04120093288	06/2018
7/13/06	ATLS CS#28326	
10/28/06	ATLS Instructor 84101	10/28/2018

AMA# 02834790044  
ACS fellow since 1990

California mandated CME in pain management and the treatment of terminally ill and dying patients per California Assembly Bill No. 487:

4/27/2002	6 units "Meeting the Challenge—A conference on Pain Management and End of Life Care" Sponsored by the Department of Family Practice, San Joaquin General Hospital and the Hospice of San Joaquin. Stockton, CA.
10/4/2003	4 units "Living While Dying: End of Life Care." Sponsored by Kaiser Permanente Northern California Region, Stockton, CA.
12/4/2004	2 units Pain Management & Alzheimer's Disease / Dementia Symposium Sponsored by Sutter Medical Center, Sacramento, CA. (Please note, the pain management approved CME was 2 hours and 5 minutes of the total 3.75 CME credit hours. I attended the entire 3.75 hours)
<b>Total 12 units</b>	

**D. Current position and address:**

Professor. Department of Surgery (Tenured July 1, 2009),  
Saint Louis University School of Medicine

Saint Louis University faculty of the Surgical Service, John Cochran VAMC  
(St. Louis VAMC) August 7, 2016 to present

Member of the SLU Surgery Resident Review Clinical Competency Committee  
from VA, July 2017- to present

Faculty Advisor for Surgery Resident Research Nov, 2012 to present

General Surgery Residency Program Director July 1, 2009 - Nov, 2012

General Surgery Residency VA Site Director 11/2019 - present

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9/2006 to pres	St. Mary's Health Center -- (Active Staff) 6420 Clayton Rd. St. Louis, MO 63117

**E. Previous Professional Experience:**

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1992-1996	Associate Professor in General Surgery Saint Louis University School of Medicine St. Louis, MO
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8/1996-12/2001    Vice Chairman, Department of Surgery  
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2/2002-4/2005    Vice Chairman, Department of Surgery  
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10/2007-8/1/2008 Co-Director, Pediatric Trauma  
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09/2006-Present Professor of Surgery (Tenured 7/1/2009)  
 7/2009-11/2012 General Surgery Residency Director, Department of Surgery,

11/2012-present Saint Louis University School of Medicine  
 Department of Surgery Advisor of Resident Research  
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**F. Clinical Staff appointments:**

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7/1986-7/1996 General Surgery Staff - Unit II Surgery  
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4/1988-7/1996 St. Mary's Health Center -- (Courtesy Privileges)  
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9/2006 to pres St. Mary's Health Center -- (Active Staff)

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9/1990-8/1996 9/2006-pres	Cardinal Glennon Children's Hospital 1465 South Grand Blvd. St. Louis, MO 63104 (Active Staff)
8/1996-12/2001	Foster G. McGaw Hospital Department of Surgery Loyola University, Chicago Stritch School of Medicine 2160 South First Avenue Maywood, IL 60153 (708) 327-2899
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**G. Professional Society Membership:**

1975-1988	American Chemical Society
1975-pres	American Medical Association
1982-1996	Missouri State Medical Association
1982-1996	St. Louis Metropolitan Medical Society
1987-2002	Society of American Gastrointestinal Endoscopic Surgeons (SAGES)
1987-1990	American College of Surgeons (Candidate Group)
1988-pres	Association for Surgical Education
2009-pres	Association of Program Directors in Surgery
1988-1997	St. Louis Surgical Society
1992-1995	Counselor
1996	President-elect, (Moved to Chicago in the Summer of 1996, but organized and presented the Fall Panel in November 1996.)
2005-to present	Member, St. Louis Surgical Society
1988-2002	American Society of Gastrointestinal Endoscopy
1988-2002	The Association of Veteran's Administration Surgeons
1989-1993	Southern Medical Association
1989-2002	The Southwestern Surgical Society
1990-pres	American College of Surgeons (Fellow)
2007-pres	Annual <i>ad hoc</i> fellowship interviewer
1990-1996	Fellow - American College of Surgeons - Missouri Chapter
2012 to present	
2012-2015	State Councilor to the Board, MO Chapter, American College of Surgeons
2015-2017	Vice-President, Missouri Chapter, American College of Surgeons
5/2017 - 5/2018	President, Missouri Chapter, American College of Surgeons
5/2018-to present	Past President, Missouri Chapter, American College of Surgeons
1991-1998	The Society of Laparoendoscopic Surgeons

1993-2002	American Gastroenterological Association
1993-2002	Association for Academic Surgery
1996-2002	Society of Surgeons of the Alimentary Tract
1997-2002	Chicago Surgical Society
1999-2002	American College of Physician Executives

NB: Due to indebtedness incurred during my advocacy for Veteran Patients in the litigation of *Andrus v VA* (US Court of Appeals for the Federal Circuit, Case 03-3162), only the American Medical Association, the American College of Surgeons, the St. Louis Surgical Society, the Association for Surgical Education, and the Association of Program Directors in Surgery dues were continued.

#### H. Honorary Societies, Honors and Awards:

1974-pres	Alpha Sigma Nu-Nat'l Jesuit Honor Society
1980	Candlelighter's Award - Outstanding resident involved in the care of hematologic-oncology patients
1984	House Officer of the year -- Saint Louis University
1991	AMA Physician's Recognition Award in Continuing Medical Education
1994	Listing in American Men and Women of Science
1994-1995	Selected Honored Member National Directory of Who's Who
1995-1996	Selected Honored Member National Directory of Excellence of Who's Who
1996	President-elect, St. Louis Surgical Society (moved to Chicago so the president term was completed by Terence Wade, M.D., F.A.C.S.)
1996-1999	AMA Physician's Recognition Award in Continuing Medical Education with Special Commendation for Self-Directed Learning
6/19/98	Attending Physician of the Year Award, Loyola University Stritch School of Medicine, "In recognition of his outstanding efforts as teacher, mentor and role model." Selected by the first year residents of the Department of Surgery at Loyola University Medical Center
2/6/99	Certificate of Recognition--Philippine Medical Association in Chicago for being a lecturer on "Laparoscopic Surgery: A review and update."
9/27/99	DVA Special Contribution Award, Hines Hospital Nutrition Support Team/Home Infusion Program
12/10/99	Interviewed by the U.S. Department of Veterans Affairs, Veterans Health Administration 1999 Under Secretary for Health Commission for the position of Under Secretary for Health, Veterans Health Administration.

- 5/4/01 Hines VAH Director's presentation of "A Certificate of Recognition of Excellence from the NSQIP" (VA National Surgery Quality Improvement Program) which states: "For LOW outlier status which indicates that risk-adjusted outcomes were better than average VAMC in: All Non-Cardiac Surgery during fiscal year 2000."
- 10/19/01 At the Loyola University/Stritch School of Medicine St. Luke's Dinner Dance announced as one of the nominees for the "Faculty of the Year Award" for the last 4 consecutive years of my five years on the faculty.
- 12/20/01 **U.S. Department of Veterans Affairs Commendation:** "The Hospital Ethics Committee (HEC) awards this Commendation to Charles H. Andrus, M.D., Chief, Surgical Service, Edward Hines, Jr. VA Hospital and Professor of Surgery, Loyola University Stritch School of Medicine in recognition of his extraordinary courage, dedication and contributions to ethical practices in healthcare. In clinical practice and as the Chief of Surgical Service, Dr. Andrus has been an exemplary ethical practitioner and leader. As a clinician, he has been a forthright advocate of the need of compassionate, respectful and candid dialogue between patients, their family members and caregivers regarding the moral tensions and emotional turmoil that often arise at the end-of-life. His sensitivity to and advocacy for these issues and the delicate mediation and decision-making they require have been inspirational. Furthermore, in every respect, he has been an outspoken, articulate and passionate champion of the need for constant vigilance about the ethical implications of physician practices. In a most effective way, his leadership style has been his example. The entire hospital community is indebted to him for the impact that he has had on our patients and their family member. He is looked upon with great respect and held in great esteem by his colleagues who have been honored by his presence. As a result of his admirable qualities, it is with great pleasure that the HEC commends Dr. Andrus for his inspirational contributions and leadership. We wish him well and God's speed in his new endeavors.
- Barbara Temeck, M.D. Gerald J. Mozdierz, Ph.D.  
Chief of Staff Chairman, Hospital Ethics Committee
- 7/17/02 San Joaquin General Hospital—Physician Recognition Award presented by Dale Bishop, M.D., Medical Director
- 12/7/07 Spirit of Saint Ignatius Service Award in recognition of extraordinary service, Department of Surgery,  
Saint Louis University School of Medicine
- 7/8/08 "*Positively Outstanding Physician*", Target 100 Physician Award, Target 100 Physician Satisfaction Team, Saint Louis University Hospital
- 10/17/2008 St. Luke's Award: *Faithful Healer*, SSMCardinal Glennon Children's Medical Center
- 2/4/09 "*Positively Outstanding Physician*", Target 100 Physician Award, Target 100 Physician Satisfaction Team, Saint Louis University Hospital
- 5/14/2009 The Leonard Tow Humanism in Medicine Award, The Arnold P. Gold Foundation, awarded at the Graduation Convocation of the Class of 2009, St. Louis University School of Medicine

5/20/2009	2008 Saint Louis University, Department of Surgery: <i>Best Attending Award</i>
2008-2009	“Exceptional Pin”, Cardinal Glennon’s World Championship Service (WCS) program, awarded by the World Championship Service Celebration and Recognition Committee, SSM Cardinal Glennon Children’s Medical Center (~6 times during this period)
2009	Top Docs, SSM Cardinal Glennon Children’s Hospital, St.Louis, MO
2010-2011	Vallee L William Award for Excellence in Surgical Education, Department of Surgery, Saint Louis University School of Medicine
2011	Service Award: on behalf of the patients, families and staff of SSM Cardinal Glennon Children’s Medical Center: “Many thanks for your support, skill, and compassion”
2011	Nominated for Caring Physician Award, Saint Louis University Hospital, St. Louis, MO
2013	Letter of Commendation regarding care of a patient from Philip Alderson, M.D., Dean, Saint Louis University School of Medicine, February 20, 2013
2015	Award for best teacher by last junior class evaluation, June 10, 2015
2016	“Twenty years of Dedicated Service”, Saint Louis University
2018	A gavel as the outgoing President, Missouri Chapter, American College of Surgeons
2019	Nominated (1 of 3 faculty nominees but not final awardee) for the Annual Overall Humanism Award: “ <i>The Humanism in Education Award</i> ” by the School of Medicine Class of 2019, Saint Louis University School of Medicine, St. Louis, MO. (Awards Banquet, February 1, 2019)
12/2/2019	2019 VA St. Louis Medical Staff Award: Dr. Andrus is a staff physician in the Surgical Service’s Section of General Surgery is recognized by his peers for his excellence in patient care, teaching, integrity, and research. He has over 20 years of service in VAH, and the majority of that time has been dedicated to the care of our Veterans at the John Cochran VA. Dr. Andrus is an experienced researcher and clinician and has served on numerous committees and in many leadership roles. His peers praise him for “instilling passion for surgery in his residents” and “teaching residents how to care for patients at the bedside”. He has played an integral role in the day to day function and coverage of general surgery clinical services and is known for his multidisciplinary approach to patient care and commitment to considering the biopsychosocial needs of his patients. He has continued to deliver the highest quality of care to our Veterans and his colleagues and patients alike have benefited greatly from his knowledge, experience, compassion, and dedication.
6/2020 - present	Annual Charles H. Andrus, M.D., F.A.C.S. for the most outstanding Surgery Intern: 2019 – 2020 Kristen Dougherty 2020 – 2021 Emily Mann

**I. Professional Services:**

**I. Committee memberships:**

*Saint Louis University Medical Center 1986-1996*

1987-1988	Utilization Review Committee
1988-1992	Environmental Protection Committee
1987-1996	Endoscopy Committee Chairman, July 1990-June 1992
1988-1996	Chairman, Surgical Department Conference (Grand Rounds) Committee
1990-1992	Quality Improvement Committee
12/93-12/95	Board of Directors - University Medical Group (UMG)

*John Cochran Veterans Administration Medical Center 1986-1996*

1987 - 1991	Chief, Unit II Surgery, Surgical Service, St. Louis VAMC
1987-1990	Quality Assurance Committee
1987-1989	Surgical Representative, Nutritional Support Committee
1988	Medical Staff Bylaws Revision Committee
1987-5/90	Medipro Surgical Reviewer for District #21
1988-1990	Medipro District Representative for District #21
1988-1989	Ad Hoc Committee for Revisions of Chief of Staff S.O.P.'s with Regards to Medications
1989-1992	Chairman, Laser Safety Committee
1990-1996	Chairman, Case Review and Tissue Committee
1990-1992	IRM Committee (Clinical Implementation of the Decentralized Hospital Computer Program)
11/90-8/92 10/92-11/95	Clinical Executive Board QA/QI Committee of the Medical Staff
10/94-11/95	Chairman, QA/QI Committee of the Medical Staff
10/94-1996	Secretary of the Medical Staff
10/94-1996	Member of Professional Standards Board



10/94-1996      Member of the Executive Committee of the Medical Staff (ECMS)  
ex-officio

***John Cochran Veterans Administration Medical Center 2016 - to present***

2017 - pres      Appointed Surgical Service representative to several Root Cause  
analysis committees

2017 - pres      Appointed *ad hoc* reviewer for Cases submitted to the VISN and John  
Cochran VAMC from the Board of Veterans Appeals (BVA)

2018 - pres      Chief, Unit II General Surgery, John Cochran (STL) VAMC

2018 - pres      Saint Louis University, Department of Surgery, General Surgery  
residency administrator regarding Surgery residents assigned to Unit  
II General Surgery, John Cochran (STL) VAMC

2019 - pres      St. Louis VAMC Transfusion Committee

***Edward Hines, Jr. VAH 1996 - 2002***

***1996 - 2002      Chief of Surgery***

1996-1/01      Quality Improvement Team (discontinued)

1996-2002      Medical Executive Committee

1996-2002      Professional Standards Board

1996-1/01      Hines Stacking Committee (discontinued)

1996-2001      Dean's Committee

10/1996      Chairman, Surgical Consolidation Task Force Meeting  
(NCVAMC/Hines)

11/1996      Member, VISN 12 Cardiac Surgery Work Group

1997-2002      Member, Resources Management Committee

Spring 1998      Member, VISN 12 Cardiac Surgery Task Group

Spring 1998      Member, COS Search Committee

Spring 1998      Member, ACOS Search Committee

9/97-2002      Member and QA/Utilization Review data collector  
OR/PAR Committee

12/98-pres	Member of the Utilization Management Committee
12/98-pres	Member of the Medical Records Committee
4/00-pres	Member of the Executive Council of the Clinical Staff (ECCS)
9/00-5/01	Member of the Leadership Council
10/00-3/01	Capital Asset Realignment for Enhanced Services (CARE) Clinical Task Force
12/00-1/01	Member, Associate Director Search Committee
	Member of the Dean's Committee for the St. Louis VAMC

***Loyola University Medical Center. 1996 - 2002***

<b><i>1996 - 2001</i></b>	<b><i>Professor and Vice-Chairman, Department of Surgery, Loyola University School of Medicine</i></b>
1996-2001	Executive/Finance Committee, Department of Surgery
1997-2001	Member, Search Committee for the Chair of the Department of Neurosurgery
2/2001	LCME Graduate Medical Education committee member

***San Joaquin General Hospital 2002 - 2005***

<b><i>2002 - 2005</i></b>	<b><i>Vice-Chairman, Department of Surgery</i></b>
2002-4/2005	Chairman, Tissue and Transfusion Committee
2002-4/2005	Member, San Joaquin General Hospital Institutional Review Board
7/2003-4/2005	Vice-president/ President-elect of the Medical Staff, San Joaquin General Hospital Medical Staff
7/2003-4/2005	Member of the SJGH Medical Executive Committee
7/2003-4/2005	Member of the Joint Conference Committee between representatives of SJGH and the San Joaquin Board of Supervisors
7/2003-4/2005	SJGH Medical Staff Bylaws Committee

***SSM DePaul Health Center 2005 - 2006***

***2005 - 2006      Trauma Medical Director***

2005-2006	Chairman, Trauma Peer Review Committee
2005-2006	Member, General Surgery Peer Review Committee
2005-2006	Member, Critical Care Committee
2005-2006	Co-director, Emergency Medical Services, SSM DePaul Health Center
2005-2006	Member, Missouri District #1 Committee on Applicants of the American College of Surgeons
2005-2006	Member, Safety/Environmental of Care Committee

***Saint Louis University Hospital***

9/2005-2011	Frequent attendee, Missouri State Advisory Council to the Governor on EMS and Trauma
2005-pres	Regular monthly member of the Surgery Residency Curriculum Committee
9/2006 - 11/14/2007	Trauma Medical Director
9/2006 - 11/14/2007	Chair, bimonthly Trauma Peer Review
9/2006 - 11/14/2007	Chair, monthly Trauma/ED Conference
9/2006 - 11/14/2007	Chair, weekly Trauma Multidisciplinary Conference and Trauma Peer Review
9/2006-2011	Member, Operating Room Committee
9/2006 - 11/14/2007	Quality Assurance Chair, IL Region 4 Trauma Committee
2006-2006	Associate Director of Critical Care for Trauma Services
7/2009-	Residency Director, Department of Surgery,
11/2012	Saint Louis University School of Medicine
7/2009-	Member of the GME Committee of Saint Louis University School of

11/2012	Medicine
11/2012-pres	Faculty Advisor for Surgery Resident Research
7/2017	Member of the Surgery Resident Review Committee from VA, July 2017- to present

***SSM Cardinal Glennon Children's Hospital***

11/14/07- 8/1/08	Interim Director of Surgery
2007-2008	Co-Director, Pediatric Trauma Services
8/2008-2011	Member of the Pediatric Trauma Committee
2007-2009	Member, Risk Management Committee
2007-2008	Chair, Trauma Peer Review Committee
11/14/07- 8/1/08	Member as the Interim Director of Surgery, Medical Executive Committee
1/2009 - 12/2011	Member as the medical staff elected <i>ad hoc representative</i> , Medical Executive Committee

***Saint Louis University***

9/1/2016 to 2018	Saint Louis University Service Appreciation Committee (faculty member of SLU HR Committee directing the Annual Service Awards Recognitions presented annually in September)
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***Saint Louis University School of Medicine, Department of Surgery***

2012 - 2020	Co-director of the Grand Rounds and Morbidity and Mortality Committee
2018 - pres	Chief, Unit II General Surgery, John Cochran (STL) VAMC
2017 - pres	Surgery Residency clinical competency committee which semi-annually reviews all General Surgery residents
2019 - pres	General Surgery VA Site Director

**II. National and Regional Committees**

1994-1996	Blue Cross/Blue Shield of Missouri
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	Statewide Digestive Panel for Practice Guidelines
1995	Missouri State Representative to the Annual Meeting of the Young Surgeons of the American College of Surgeons
1996	President-elect of the St. Louis Surgical Society
1996	Education Committee, Missouri Chapter, American College of Surgeons
1996	Councilor--Missouri Chapter American College of Surgeons
1996	Slide librarian for EGD and ERCP, Society of American Gastrointestinal Endoscopic Surgeons (SAGES)
1996	ASGE Postgraduate Education Committee Member
1996	Member of the ACS Missouri Committee on Applicants District 1
2001	Abstract reviewer for the Chicago Surgery Society
2006-2007	Chairman, Region IV, Illinois Trauma System
2013-2015	Councilor--Missouri Chapter, American College of Surgeons
2015-2017	Vice-president, Missouri Chapter, American College of Surgeons
2017 - 2018	President, Missouri Chapter, American College of Surgeons

### III. Journal Peer Reviewer

1. Surgical Endoscopy (~1990-2001)
2. Surgical Laparoscopy & Endoscopy (~1990-2001)

### J. Research Support:

1. VA Merit Review Grant -- "Evaluation of New Methods of Proximal Gastric Vagotomy (PGV)" - Three year grant (extended one additional year): October 1, 1992 - September 30, 1996. \$400,000
2. Educational Grant for the San Joaquin General Hospital Surgery Residency from Wyeth Pharmaceuticals, December 17, 2002. \$1,200

### Research Projects:

1. Hiler AM, Cederstrad S, Gill R, Brink D, Andrus CH, Wanken Z, Zawin J: The clinical presentation of *Entrobis vermicularis* as a etiologic agent of appendicitis. (A. Hiler has developed the IRB submission, submitted to the Saint Louis

University IRB Committee, and received initial IRB approval in November 2010 and has received continue annual approval.: IRB# 16927, 325 charts were reviewed by November 2011; IRB# 16927 renewed November 2011 with Dr. Andrus as PI with a total of 450 charts reviewed by September 2012; IRB# 16927 was renewed again in November 2013, 2014, 2015, 2016 with Dr. Andrus as PI). Discontinued November 2017.

2. Hopping J, Andrus C, Wiley E, Chen R: Is obesity a direct cause of childhood gallstone disease? IRB# 23197. Retrospective chart review of children undergoing cholecystectomy. Roughly 2/3 of the available charts have been reviewed. (Has been placed on hold, 2015)
3. Andrus CH, Andrus PC, Foster VE, Krishi P: Foreign Body Location and Retrieval Device. Patent Pending: Serial Number 13/605,086, submitted September 6, 2012, Attorney Docket No. 31065-32 (SLU 12-006), AT Ref No: 31065-32, U.S. Patent: 8,768,435 B2, July 1, 2014. Have participated as the faculty advisor to this project in the development of the clamp and its presentations in the SLU School of Engineering in I2P regional and national competitions. Will continue to work with the Office of Technology Development, Saint Louis University.  
Faculty advisor, intellectual contributor, and facilitator in the development of Sonograb : Foreign Body Location and Retrieval Device. Patent pending—filed on Sept 6, 2012 as application serial no. 13/605,086. Inventors: Charles Hiram Andrus, Patrick Christopher Andrus, Virginia E. Foster, and Peddada Krishi. Patent submission through the Office of Technology Management, Saint Louis University. Sonograb presented in international competition, Idea to Product (I2P), Stockholm, Sweden, Nov 16-17, 2012 by Patrick Andrus (Charles Andrus, M.D., faculty advisor). Awarded 2<sup>nd</sup> prize in the Life Sciences category. Patent awarded: July 1, 2014.
4. Charles Harold Andrus, MHA, Charles Hiram Andrus, M.D., F.A.C.S, and Pamela B. Andrus, M.A., CCC-SP: *Mitochondrial Encephalopathy—A family case study of epileptic seizures, the ketogenic diet, and metabolic disorders*. John C. Kennell, PhD, Courtney F. Andrus, PA-C, R.D., L.D., Regina Lynch-Linsey, BS, MA eds. St. Peters, MO: Business Building Books, 2012. (In the summer and fall 2016, final stages of editing and proofing)
5. Andrus CH, Andrus CH, Andrus PB: The ketogenic diet as an energy treatment of complex I deficiencies. Pediatric Research Days, SSM Cardinal Glennon Children's Hospital, SLUSOM, April 11, 2013. (Chapter 7: Charles Harold Andrus, MHA, Charles Hiram Andrus, M.D., F.A.C.S, and Pamela B. Andrus, M.A., CCC-SP: *Mitochondrial Encephalopathy—A family case study of epileptic seizures, the ketogenic diet, and metabolic disorders*. Kennell, Andrus, Lynch-Linsey, eds. 2016)

***The following which were podium or poster presentations at the Annual MO state ACS meeting in May-June—2013, 2014, 2015, 2016, 2017, 2018, and 2019:***



6. Khan AA, Jurgens JM, Hubble AA, Andrus CH: Thrombelastographic assessment in chronic disseminated intravascular coagulation (DIC).
7. Zahra A, Witte AJ, Krampert RM, Andrus CH: Coagulation management during an operation on a uremic patient.
8. Jasra B, Naunheim KS, Ely E, Andrus CH: Thymoma secreting ectopic parathyroid hormone concomitantly with tertiary hyperparathyroidism.
9. Nguyen KP, Andrus MF, Naunhiem KS, Andrus CH: Laparoscopic repair of a parahiatal hernia.
10. Sun Y, Williams MS, Peterson BG, Andrus CH: Acute and chronic central abdominal venous thrombosis three decades after necrotizing enterocolitis.
11. Gorantla K, Andrus CH, Andrus PC, Andrus CH: Crush protection due to pediatric chest wall malleability?
12. Sen R, Sun Y, Andrus MF, Leuhr EA, Andrus CH: Transappendiceal ileoscopy during operative reduction of an ileocolic intussusception.
13. Farrell KA, Salter EE, Andrus CH: The 150 Year Promise that Irrevocably Impacts Surgical Education to this Day.
14. Patel S, Sun A, Andrus CH: Is the Cold Appendix Acceptable in this Era of Advanced Imaging? Carlson EAJ, Sun Y, Andrus CH: Resolution of a Decade of Chronic Abdominal Pain after a Laparoscopic Incisional Hernia Repair.
15. Lobb Jennifer, MD, Diggs L, MD, Andrus CH: Surgical Management of AIDS/HIV Related Gastrointestinal Disease in the Modern Era: A Case Report.
16. LaPlante J, Glasgow S, Andrus C: Terminal ileal adenocarcinoma and synchronous renal cell CA: A Case Report.
17. Dwyer, Emma, Andrus CH: A forgotten chronic deficiency after a historic operation (Vitamin B12 deficiency 7 years after total gastrectomy). MO-Chapter, American College of Surgeons, 51<sup>st</sup> Annual Professional Meeting, Camden on the Lake, Lake of the Ozarks, Missouri, May 11, 2018. (Dwyer discussant: Podium presentation)
18. Henderson CN, Andrus CH: The evaluation and treatment of dyspepsia. MO-Chapter, American College of Surgeons, 51<sup>st</sup> Annual Professional Meeting, Camden on the Lake, Lake of the Ozarks, Missouri, May 11, 2018. (Andrus discussant: Podium presentation)

19. Andrus CH: Presidential Address: The ACS Pledge – Relevance in the Practice of Surgery in the 21<sup>st</sup> Century. President, MO-Chapter, American College of Surgeons, 51<sup>st</sup> Annual Professional Meeting, Camden on the Lake, Lake of the Ozarks, Missouri, May 11, 2018. (Andrus discussant: Podium presentation)
20. Khouri AJ, Hou P, Andrus CH: Ischemic colitis in radiographic colonic lipohyperplasia: Getting it right for the wrong reason. MO-Chapter, American College of Surgeons, 52<sup>nd</sup> Annual Professional Meeting, Camden on the Lake, Lake of the Ozarks, Missouri, May 4, 2019.

### Previous projects archived:

1. 2002-2005. The Diversity, Epidemiology and Outcomes in Human Trauma Associated with the Livestock in an Urban/Rural County of California, IRB#02-50. A retrospective study with the accrual of approximately 75 patients. Charles Andrus, M.D., Principal Investigator; Co-investigators: Eduardo Villaseñor, M.D.; Mohammed Ibrahim, M.D.; Robert Yavrouian, M.D.; Nathaniel Matolo, M.D.; Ahmed Mahmoud, M.D., faculty advisor; Colburn Ward, Ph.D.; and Ziad Ali. Initial draft of the resultant paper as of April 8, 2005-pres: Ali ZA, Andrus CH, Mahmoud A, Matolo NM, Ward CC: Don't Drink and Drive Cattle or Horses: The diversity, epidemiology and outcomes in human trauma associated with the livestock in an urban/rural county of California.
2. 2005-2005. ERCP during Laparoscopic Cholecystectomy, IRB #04-71. A retrospective study comparing preoperative, intraoperative, and postoperative ERCP. John Foster, M.D., Principal Investigator; Co-investigators: Hien Pham, M.D.; Charles Andrus, M.D., faculty advisor; James Bresnahan, M.D.; Ahmed Mahmoud, M.D.; Nathaniel Matolo, M.D.; Colburn Ward, Ph.D. (Data collection and some of the statistical analysis completed regarding an initial resultant paper: Andrus CH, Ali ZA, Mahmoud A, Ward CC, Matolo NM: Prospectively predicting the indications for intraoperative cholangiography during laparoscopic cholecystectomy—Should we just flip a coin?)
3. 2005. Severity of Injuries Sustained in Motorcycle versus Other Vehicular Accidents, #04-72. A retrospective study evaluating the severity of injury in motorcycle accidents locally in San Joaquin County responding to the research question raised when the California Highway Patrol data (1997-2001) was evaluated demonstrating twice the mortality rate among licensed motorcycle drivers vs. mortality in all other licensed vehicular accidents but a injury rate statistically identical between the two groups. Robert Keenan, M.D., Principal Investigator; Christopher Solis, M.D., Charles Andrus, M.D., faculty advisor; Nathaniel Matolo, M.D.; Colburn Ward, Ph.D.
4. 2005. Necrotizing Fasciitis, IRB# 04-73. A retrospective study evaluating the epidemic of necrotizing fasciitis in California mainly associated with black-tar heroin utilization and the high mortality seen in *C. sordellii* infections. Ronald Barbosa, M.D., Principal Investigator; Tony Chang, M.D.; Dennis Schoch, M.D.; Charles Andrus, M.D.; Nathaniel Matolo, M.D.; Ahmed Mahmoud, M.D.; Colburn Ward, Ph.D.; John E. Baker, M.D.; Hong Li, M.D.
5. 2005. Application to become the co-investigator for San Joaquin County, California in the multi-institutional study sponsored by the NIAID of the NIH entitled: A Phase I/II Randomized, Placebo-controlled Trial to Assess the Safety and Efficacy of Intravenous Immunoglobulin G (Omr-IgG-am™) Containing High Anti-West Nile Virus Antibody Titers in Patients with, or at High Risk for Progression to West Nile Virus (WNV) Encephalitis and/or Myelitis (CASP #210)(DMID#03-107), IRB#04-74. Richard J. Whitley, M.D., University of Alabama at Birmingham, Principal Investigator; Charles H. Andrus, M.D., F.A.C.S., local co-investigator; named collaborators with local co-investigator: Sheela Kapre, M.D., Chairperson, Dept. of Medicine, SJGH; Rod Felber, M.D., Vice-Chairperson, Dept. of Medicine, SJGH; Karen Furst, M.D., M.P.H., Health Officer, San Joaquin County Public Health Services; Dale Bishop, M.D., Assistant Health Officer, San Joaquin County Public Health Services.
6. 2005. Bedside Versus Operating Room Tracheostomy, IRB#02-48. A retrospective study with the accrual of approximately 55 patients. Nathaniel Matolo, M.D., Principal Investigator; Charles Andrus, M.D., Hanlon Jen, M.D., Arvin Taneja, M.D., Samuel K.M. Liu, M.D. (Initial draft of the resultant paper as of April 8, 2005: Liu SKM, Taneja A, Jen HB, Andrus CH, Mahmoud A, Matolo N: Bedside versus operating room tracheostomy.)
7. 2009. Vasquez E, Ferguson K, Andrus CH: Closure of a gastrostomy site with the Carter-Thomason closure sure System: A case-report.
8. 2009. Grosser J, Andrus C: Preperitoneal emphysema as a cause of postoperative pain after laparoscopic appendectomy.

9. 2009. Aaron Llyod, M.D., Daniel Naughton, M.D., Charles Andrus, M.D., Chris Green, R.N., Pam Golden, R.N.: An epidemic of injuries found in all terrain vehicle (ATV) enthusiasts.
10. 2011. Andrus CH (P.I.), Aaron Scifres, M.D. (former P.I.), Christopher Aldridge, M.D., Jonathon Lusardi, MSIII, Kathryn Lindsay, Med, RN, Optimal timing of tracheostomy in severely injured elderly patients. IRB: 15975, Saint Louis University.
11. 2008. Luehr E, Andrus C: Transappendiceal ileoscopy during the operative reduction of intussusceptions in children.
12. 2008. Bailey J, Freeman C, Andrus C, other members of the SLU trauma service: Referral patterns of trauma patients to a bi-state Level I trauma service.
13. 2011. Andrus C, TBA: Bilateral traumatic pneumatoceles after a rapid acceleration/deceleration crushing chest injury.

**K. Bibliography:**

**I. Papers published, in press, or accepted for publication in peer reviewed journals**

1. Gruhn TA, Benton EV, Andrus CH: The etching of cellulose nitrate plastic. Nucl Instr Methods 119:131-133, 1974.
2. Andrus CH, Kaminski DL: Segmental hepatic resection utilizing the ultrasonic dissector. Arch Surg 121:515-521, 1986.
3. Andrus CH, Doering M, Herrmann VM, Kaminski DL: Planned reoperation for generalized intra-abdominal infection. Am J Surg 152:682-686, 1986.
4. Schlarman DE, Beinfeld MC, Andrus CH, Kaminski DL: Effects of somatostatin on acute canine experimental pancreatitis. Int J Pancreatol 2:247-255, 1987.
5. Andrus CH, Ponsky JL: The effects of irrigant temperature in upper gastrointestinal hemorrhage: A requiem for iced saline lavage. Am J Gastroenterol 82:1062-1064, 1987.
6. Vernava AM, Andrus CH, Herrmann VM, Kaminski DL: Pancreatitis after biliary tract surgery. Arch Surg 122:575-580, 1987.
7. Andrus CH, Ponsky JL: Bezoars: Classification, pathophysiology and treatment. Am J Gastroenterol 83:476-478, 1988.
8. O'Loughlin KC, Andrus CH, Kaminski DL: A simplified technique for the extirpation of the gastric bubble utilizing an endo-overtube. Am Surg 55:116-118, 1989.
9. Komenda G, Andrus CH: Infection following total hip arthroplasty. VA Pract 6:43-51, 1989.
10. Andrus CH, Swensson EE, Peterson GJ, Vernava AM, Langsfeld M: Pancreatic necrosis and abscess following rupture of an abdominal aortic aneurysm. Vascular Reports (Accepted 1986 and publication pending).
11. Westfall SH, Andrus CH, Naunheim KS: A reproducible, safe jejunostomy replacement technique by a percutaneous endoscopic method. Am Surg 56:141-143, 1990.
12. Andrus CH, Dean PA, Ponsky JL: Evaluation of safe, effective, intravenous sedation for utilization in endoscopic procedures. Surg Endosc 4:179-183, 1990.
13. Shapiro MJ, Alexander AJ, Andrus CH: Gallstones in the pancreatic duct: Endoscopic retrograde pancreatographic demonstration. J Clin Gastroenterol 12(4):454-6, 1990.
14. Kaminski DL, Andrus CH, German D, Deshpande YG: The role of prostanoids in the production of acute acalculous cholecystitis by platelet-activating factor. Ann Surg 212:455-461, 1990.

15. Larsen F, Schlarman D, Andrus C, Kaminski D: The effect of the CCK receptor antagonist CR 1409 on bile reflux pancreatitis in the opossum. *Pancreas* 6:291-297, 1991.
16. Blatner M, Wittgen CM, Andrus CH, Kaminski DL: Cystic duct cholangiography during laparoscopic cholecystectomy. *Arch Surg* 126:646-649, 1991.
17. Westfall S, Andrus C, Schlarman D, and Kaminski DL: The effect of CCK-receptor antagonists on CCK stimulated bile flow in dogs. *Surg* 109:294-300, 1991.
18. Wittgen CM, Andrus CH, Fitzgerald SD, Baudendistel LJ, Dahms TE, Kaminski DL: Analysis of the hemodynamic and ventilatory effects of laparoscopic cholecystectomy. *Arch Surg* 126:997-1001, 1991.
19. Andrus CH: Endoscopic ultrasonography: A new highly sensitive and specific diagnostic and staging technique for upper gastrointestinal tumors. *Saint Louis Metro Medicine* 13:21-23, 1991.
20. Andrus CH, Daly JL: Evaluation of Surgical Services in a Large University-Affiliated VA Hospital: Use of an In-House-Generated Quality Assurance Data Base. *So Med J* 84:1447-1450, 1991.
21. Schneider T, Fitzgerald S, LaRegina M, Kaminski D, Andrus C: Evaluation of proximal gastric vagotomy by cobaltous chloride (COCl<sub>2</sub>) chemoneurolysis in a rat model. *ACS Surgical Forum XLII*:177-179, 1991.
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23. Fitzgerald SD, Andrus CH, Baudendistel LJ, Dahms TE, Kaminski DL: Hypercarbia during carbon dioxide pneumoperitoneum. *Am J Surg* 163:186-190, 1992.
24. Schneider TA, Andrus CH: The endoscopic Congo red test during proximal gastric vagotomy: an essential procedure. *Surg Endosc* 6:16-17, 1992.
25. Schneider TA, Andrus CH: The endoscopic Congo red test during proximal gastric vagotomy: an essential procedure. (The Authors Reply). *Surg Endosc* 7:210, 1993.
26. Parra RO, Andrus CH, Boullier JA: Staging laparoscopic pelvic lymph node dissection: Comparison of results with open pelvic lymphadenectomy. *J Urol* 147:875-878, 1992.
27. Hagood PG, Mehan DJ, Worischek JH, Andrus CH, Parra RO: Laparoscopic varicocelectomy: Preliminary report of a new technique. *J Urol* 147:73-76, 1992.
28. Naunheim KS, Petruska PJ, Roy T, Andrus CH, Johnson FE, Schlueter JM, Baue AE: Preoperative chemoradiation and radiotherapy for esophageal carcinoma. *J Thorac Cardiovasc Surg* 103:887-895, 1992.

29. Parra RO, Jones JP, Andrus CH, Hagood PG: Laparoscopic diverticulectomy: Preliminary report of a new approach for the treatment of bladder diverticulum. *J Urol* 148:869-871, 1992.
30. Parra RO, Andrus CH, Jones JP, Boullier JA: Laparoscopic cystectomy: Initial report on a new treatment for the retained bladder. *J Urol* 148:1140-1144, 1992.
31. Parra RO, Andrus CH, and Boullier JA: Staging laparoscopic pelvic lymph node dissection: experience and indications. *Arch Surg* 127:1294-1297, 1992.
32. Wade TP and Andrus CH: Cardiorespiratory effects of laparotomy in patients with spinal cord injury. *Am Surg* 59:689-691, 1993.
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34. Schneider TA, Wittgen CM, Andrus CH, Kaminski DL: Comparison of minimally invasive methods of parietal cell vagotomy in a porcine model. *Surg* 112:649-655, 1992.
35. Wittgen CM, Andrus JP, Andrus CH and Kaminski DL: Cholecystectomy: Which procedure is best for the high-risk patient. *Surg Endosc* 7(5): 395-399, 1993.
36. Mehan DJ, Andrus CH, Parra RO: Laparoscopic internal spermatic vein ligation: report of a new technique. *Fertility and Sterility* 58:1263-1266, 1992.
37. Mehan DJ, Andrus CH, and Parra RO: Simultaneous laparoscopic varicocelectomy and removal of an intrascrotal atrophic testicle. *Surgical Laparoscopy & Endoscopy* 2(4):327-331, 1992.
38. Wade TP, Kaminski DL, Andrus CH: Evaluations of surgery resident performance correlate with success in board examinations. *Surgery* 113:644-648, 1993.
39. Wittgen CM, Schneider TA, Fitzgerald SD, Panneton WM, LaRegina MC, Johnson S, Kaminski DL, Andrus CH: Proximal gastric vagotomy by minimally invasive methods in an acute rat model. *Surg Endosc* 7:319-324, 1993.
40. Wittgen CM, Naunheim KS, Andrus CH, Kaminski DL: Preoperative pulmonary function evaluation for laparoscopic cholecystectomy. *Arch Surg* 128:880-886, 1993.
41. Naunheim KS, Andrus CH: Thoracoscopy resection of giant mediastinal cyst. *Ann Thor Surg* 55:156-158, 1993.
42. Andrus CH: Invited Commentary, "Hemodynamic Effects of Argon Pneumoperitoneum." [comment] *Surg Endosc* 8:322-323 1994.
43. Neuberger TJ, Wittgen CM, Schneider TA, Andrus CH, Panneton WM, Kaminski DL: Evaluation of alternative proximal gastric vagotomy technique after a nine-month interval in a rat model. *Gastroenter Endosc* 40:316-320, 1994.
44. Andrus CH: Endoscopic assessment of vascular disorders. *Sem Colon Rect Surg* 5:27-31, 1994.



45. Votapka TV, Pennington DG, McBride LR, Kaminski DL, Andrus CH, Swartz MT: Non-cardiac surgery in patients supported with mechanical circulatory support devices: A report of seven cases. *J Am Coll Surgeons* 179:318-320, 1994.
46. Wade TP, Comitolo JB, Andrus CH, Goodwin MM, Kaminski DL: Laparoscopic cancer surgery: Lessons from gallbladder cancer. *Surg Endosc* 8:698-701, 1994.
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48. Andrus CH: Letter to the Editor: Exploratory laparoscopy for perforation following colonoscopy (4:241-3, 1994). *Surg Laparosc Endosc* 4:327, 1994.
49. Marts BC, Carr SC, Andrus CH, Kaminski DL, Wade TP: Staged surgical management of cholecystocutaneous abscess. *Contemp Surg* 45:273-277, 1994.
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51. Parra RO, Hagood PG, Boullier JA, Cummings JM, Mehan DJ: Complications of laparoscopic urological surgery: Experience at Saint Louis University. *J Urol* 151:681-684, 1994.
52. Ure T, Dehghan K, Vernava III AM, Longo WE, Andrus CA, Daniel GL: Colonoscopy in the elderly. *Surg Endosc* 9:505-508, 1995.
53. Silen ML, Canvasser DA, Kurkchubasche AG, Andrus CH, and Naunheim KS: Video-assisted thoracic surgical repair of a foreamen of Bochdalek hernia. *Ann Thorac Surg* 60:448-450, 1995.
54. Wibbenmeyer LA, Wade TP, Chen RC, Turgeon RP, Meyer RC, Andrus CH: Laparoscopic cholecystectomy can disseminate in-situ gallbladder cancer. *J Am Col of Surg* 181:504-510, 1995.
55. Neuberger TJ, Andrus CH, Wittgen CM, Wade TP, Kaminski DL: Prospective comparison of helium versus carbon dioxide pneumoperitoneum. *Gastrointestinal Endoscopy* 43:38-41, 1996.
56. Naunheim KS, Landreneau RJ, Andrus CH, Ferson PF, Zachary PE, Keenan RJ: Laparoscopic fundoplication: A natural extension for the thoracic surgeon. *Ann Thorac Surg* 61:1062-1065, 1996.
57. Warner PM, Andrus CH: Hemodynamic and pulmonary implications and complications in laparoscopic surgery. *Sem Laparoscopic Surg* 4:135-138, 1997.
58. Wade TP, Feldman MS, Andrus CH: The spectrum of mucus-secreting pancreatic neoplasia. *Am J Gastroenterol* 92:154-155, 1997.

59. Damore LJ, Andrus CH, Herrmann VM, Wade TP, Kaminski DL, Kaiser GC: Prospective evaluation of a new through-the-scope nasoduodenal enteral feeding tube. *Surg Endosc* 11:460-463, 1997.
60. El-Ghazzawy AG, Gupta N, Swope TJ, Kulkarni AD, Panneton WM, Robinson SM, Niehoff ML, Kaminski DL, Andrus CH: Evaluation of benzalkonium chloride chemoneurolytic proximal gastric vagotomy. *Surg Endosc* 12:207-211, 1998.
61. Andrus CH, Cosgrove JM, Longo WE, eds. *Minimally Invasive Surgery: Principles and Outcomes*. Amsterdam, Harwood Academic Publishers, July, 1998.
62. Soweid AM, Clarkston WK, Andrus CH, Janney CG: Diagnosis and management of appendiceal mucoceles. *Dig Dis* 16:183-186, 1998.
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64. Kleinman B, Baumann M, Andrus C: Faulty design resulting in temporary pacemaker failure. *Chest* 120:684-685, 2001.
65. Andrus CH, Villasenor EG, Kettelle JB, Roth R, Sweeney AM, Matolo NM: "To Err is Human": Uniformly Reporting Medical Errors and Near Misses: A Naïve, Costly and Misdirected Goal. *J Am Coll Surg* 196(6): 911-918, June 2003. [Was requested on January 29, 2004 by Doris Goldstein, M.L.S., M.A., Director, National Reference Center for Bioethics Literature for inclusion in the collection of published bioethical articles of the Joseph and Rose Kennedy Institute of Ethics, Georgetown University, National Reference Center for Bioethics Literature supported by the U.S. National Library of Medicine. Added to the library's "ETHX on the Web" at <http://bioethics.georgetown.edu> in August, 2004.]
66. Mahmoud A, Andrus CH, Matolo NM, Ward CC: Directed postgraduate study result in quantitative improvement in ABSITE scores. *Am J Surg* 191;812-816, 2006.
67. Leon L, Labropoulos N, Hudlin CI, Macbeth AG, Matolo N, Andrus CH: Accessory Spleen Rupture in a Patient with Previous Traumatic Splenectomy. *J Trauma* 60:901-903, 2006.

## II. Book chapters:

1. Drucker WR, Foster RS, Gamelli RL, et al.: *Clinical Surgery* (Andrus -- one of several surgical resident editors) (St. Louis: C.V. Mosby, 1987).
2. Andrus CH, Kaminski DL: Specialized Therapeutic Considerations for Patients with Hepatobiliary Disease. *Essentials of Clinical Hepatology*. Gholson CF, Bacon BR editors. Mosby, 1992, St. Louis, pp. 134-154.

3. Andrus CH and the Missouri Statewide Practice Guidelines for Digestive Conditions Committee: Practice Guidelines: Digestive. Alliance, BlueCross BlueShield, 1995.
4. Andrus CH: Set up of the Operating Suite and Instrumentation for Laparoscopy. In: Parra RO, Boullier, JA (eds.). Urologic Laparoscopic Surgery. McGraw Hill, Inc., Blacklick, Ohio, 1995.
5. Andrus CH, Wittgen CM, Parra RO: Physiologic and Anesthetic Principles of Laparoscopy. In: Parra RO, Boullier JA (eds.). Urologic Laparoscopic Surgery. McGraw Hill, Inc., Blacklick, Ohio, 1995.
6. Andrus CH: Pneumoperitoneum during urologic laparoscopy. In: Parra RO, Boullier JA (eds.). Urologic Laparoscopic Surgery. McGraw Hill, Inc., Blacklick, Ohio, 1995.
7. Andrus CH, Naunheim KS, Wittgen CM: Anesthetic considerations. In: MacFadyen BV, Ponsky JL (eds.): Operative Laparoscopy & Thoracoscopy. Lippincott-Raven, Philadelphia, PA, 1996.
8. Laureano BA, Andrus CH, Kaminski DL. Cardiovascular changes during laparoscopy. In: Rosenthal RJ, Friedman RL, Phillips EH. The pathophysiology of pneumoperitoneum. New York: Springer; 1991, pp. 77-84.
9. Deveaux PG, Andrus CH: Minimally Invasive Surgery in the Immunocompromised Patient. Minimally Invasive Surgery: Principles and Outcomes. CH Andrus, JM Cosgrove, WE Longo, eds. Amsterdam, Harwood Academic Publishers, July, 1998, pp. 377-380.
10. Chough EK, Andrus CH: Physiology of Pneumoperitoneum. Minimally Invasive Surgery: Principles and Outcomes. CH Andrus, JM Cosgrove, WE Longo, eds. Amsterdam, Harwood Academic Publishers, July, 1998, pp. 13-18.
11. Andrus CH, Miller SH: Small Bowel Enteroscopy. The SAGES Manual: Fundamentals of Laparoscopy and GI Endoscopy. Carol Scott-Conner, editor. Springer-Verlag, New York, NY, 1998, pp. 480-484.
12. Schaffner J, Andrus CH: GI Bleeding. Multidisciplinary Critical Care Board Review Course. Society of Critical Care Medicine, July, 1998, pp. 127-137.
13. Napolitano M, Andrus CH: Preoperative and Postoperative Care of the Flexible Endoscopy Patient. Mastery of Endoscopic and Laparoscopic Surgery, eds.: W.Stephen Eubanks, Lee L. Swanstrom, Nathaniel J. Soper. (Philadelphia: Lippincott Williams & Wilkins, 1999), pp. 12-17.
14. Andrus CH, Miller SH: Chapter 59: Small Bowel Enteroscopy. The SAGES Manual: Fundamentals of Laparoscopy and GI Endoscopy, Second Edition. Carol Scott-Conner, M.D., F.A.C.S., editor. Springer-Verlag, New York, NY, 2006.

### III. Abstracts

1. O'Loughlin KC, Andrus CH, and Kaminski DL: A simplified technique for the extirpation of the gastric bubble utilizing an endo overtube. *Am Surg* 54:526, 1988.
2. Andrus CH, Dean PA, Ponsky JL: Evaluation of safe effective intravenous sedation for utilization in endoscopic procedures. *Surg Endosc* 4:56, 1990.
3. Vernava AM, Beckman R, Andrus C, Johnson F, Herrmann V, Kaminski DL: Tangential colostomy preferred for temporary fecal diversion. *Dis Colon Rectum* 33(3):26, 1990.
4. Vernava AM, Doering M, Andrus C, Johnson F, Herrmann V, Kaminski D: Flow cytometry in colorectal cancer. *So Med J*, pp. 2S-11, 1990.
5. Andrus CH, Daly JL: Utilization of an in-house generated quality assurance database for the evaluation of the surgical services in a large university-affiliated VA hospital. *So Med J*, pp. 2S-79, 1990.
6. Mehan DJ, Hagood PG, Worischek JH, Andrus CH, and Parra R: Laparoscopic varicocelectomy: Preliminary report of a new technique, Part I. *J Urol* 145:242A, #117, 1991.
7. Boullier JA, Andrus CH, Parra RO: Staging laparoscopic pelvic lymph node dissection, initial report. *J Urol* 145:423A, #841, 1991.
8. Hagood PG, Mehan DJ, Worischek JH, Andrus CH, Parra RO: Laparoscopic varicocelectomy. (Video). *J Urol* 145:204A, #V-51, 1991.
9. Andrus CH, Wittgen CM, Naunheim KS, McManama GP, Rinehart GC, Clarkson WK, Wade TP: Densitometric evaluation of endoscopic ultrasonography. *Gastrointest Endosc* 38:271-272, 1992.
10. Wittgen CM, Andrus JP, Andrus CH, Kaminski DL: Cholecystectomy: Which procedure is best for the high risk patient? *Surg Endosc* 6:88, 1992.
11. Petruska P, Naunheim K, Roy T, Andrus C, Johnson F, Daniel F, Spencer L, Baue A: Preoperative chemoradiation for esophageal carcinoma. *Proc ASCO* 11:182, 1992.
12. Schneider TA, LaRegina MC, Fitzgerald SD, Wittgen CM, Virgo KS, Kaminski DL, Andrus CH: Confirmation of parietal cell distribution by histologic and Congo red techniques in a porcine model. *Gastroenterology* 102:A161, 1992.
13. Wittgen CM, Neuberger TJ, Schneider TA, Andrus CH, Panneton WM, Kaminski DL: Evaluation of alternate PGV techniques in a chronic rat model. *Gastrointestinal Endoscopy* 39 (2)269.
14. Beckman R, Andrus C, Johnson F, Herrmann V, Kaminski D: Colostomy formation and closure. *Proc Mo Chapt Am Coll Surg* 21:17, 1988.
15. Neuberger TJ, Andrus CH, Wittgen CM, Wade TP, Kaminski DL: Prospective comparison of helium versus carbon dioxide pneumoperitoneum. *Gastrointestinal Endoscopy* 40:P30, 1994.

16. Marts BC, Carr SC, Andrus CH, Kaminski DL, Wade TP: Staged surgical management of cholecystocutaneous abscess. *Contemporary Surgery* 45(5):273-277, 1994.
17. Damore LJ, Andrus CH, Herrmann VM, Wade TP, Kaminski DL, Kaiser GC: Prospective evaluation of a new through-the-scope nasoduodenal enteral feeding tube. *S162 Surg Endosc* 10: 212, 1996.
18. El-Ghazzawy AG, Gupta N, Swope TJ, Kulkarni AD, Panneton WM, Robinson SM, Niehoff ML, Kaminski DL, Andrus CH: Evaluation of benzalkonium chloride chemoneurolytic proximal gastric vagotomy. *Surg Endosc* 11:196, 1997. (Abstract & Poster, SAGES, March, 1997)
19. Andrus CH, Miller GA, Sunwoo YC, Nowlin LJ, Millis BM, Ellison JA, Qualls C, Johnson FE: The quality assurance evaluation of an abdominal wound evisceration epidemic!? Poster Southwestern Surgical Congress, April, 1997.
20. Zapotocky T, Heintz-Miller K, Brayshaw M, Foley S, Lau MT, Byrne R, Andrus CH: A comparison of foley catheters as feeding tubes versus standard gastrostomy tubes. Poster N0044, ASPEN, 25th Clinical Congress, Chicago, IL, January 21-24, 2001.
21. Foley, S, Clemmer M, Martling W, Williams D, Heintz-Miller K, Lau MT, Byrne R, Andrus CH, Reinhardt G: Hypoalbuminemia and mortality in a hospitalized veteran population: Comparison over 20 years. Poster N0014, ASPEN, 25th Clinical Congress, Chicago, IL, January 21-24, 2001.
22. Andrus CH, Kleinman BS, Mozdierz G, Sinacore JM, Garthwaite TA: Mortality outcomes and attending surgeon presence at the time of operation. Submitted November 15, 2002 for consideration for presentation at the 23<sup>rd</sup> Annual Meeting of the Association for Surgical Education, Vancouver, B.C., Canada, May 6-8, 2003. Accepted for podium presentation for May 7, 2003.
23. Andrus CH, Mozdierz GJ, Mahmoud AM, Kettelle JB, Matolo NM: "Primum Non Nocere" vs. "the Bottom-line" in Surgical Education: Submitted December 3, 2002 for consideration for presentation at the Annual Meeting of the Association of Program Directors in Surgery, Vancouver, B.C., Canada, May 6-8, 2003. Rejected January, 2003.
24. Vasquez E, Scifres A, Lindsay K, Bailey J, Freeman C, Andrus C. Utilization in the treatment of victims of traumatic cardiopulmonary arrest. Submitted to Missouri Chapter of American College of Surgeons, April 2007.

**L. Current and past teaching responsibilities:**

1. Andrus CH: Indications and uses for flexible sigmoidoscopy in the family practice office: Illinois Academy of Family Physicians, St. Elizabeth's Hospital. Belleville, IL, October 29, 1987.
2. Andrus CH, Herrmann V: Total enteral nutrition. Staff of Grand Island VAH, Grand Island, NE, December 3, 1987.
3. Andrus CH: Selection of appropriate enteral feeding tubes. ASPEN, St. Louis, MO, September 8, 1988.

4. Andrus CH: Endoscopically placed feeding tubes: indications and methods. ASPEN, St. Louis, MO, September 9, 1988.
5. Andrus CH: The physician's role in the hyperalimentation team. RMEC. Saint Louis VAMC, St. Louis, MO, April 12, 1989.
6. Andrus CH, Wittgen CM: Advances in laparoscopic diagnosis and therapy. Gastroenterology Grand Rounds, Saint Louis University, October 13, 1989.
7. Andrus CH: Advances in surgical endoscopy "Away From Winter-1990", Saint Louis University, St. Louis, MO, February 11, 1990.
8. Andrus CH: AIDS and the health care worker. Labor Health Institute Staff, Saint Louis, MO, April 26, 1990.
9. Andrus CH: Surgical endoscopy. St. Joseph's Hospital Surgical Staff, Saint Joseph's Hospital, St. Louis, MO, May 23, 1990.
10. Andrus CH: Laparoscopy and the general surgeon. Lab demonstrations of laparoscopic cholecystectomy. St. Mary's Health Center, St. Louis, MO, June 9, 1990.
11. Andrus CH: Cholangiography during laparoscopic cholecystectomy. Lab demonstration of laparoscopic cholecystectomy. Mt. Sinai Medical Center, Cleveland, OH, July 6-7, 1990.
12. Andrus CH: Advances in laparoscopic surgery. Gastroenterology Grand Rounds, Saint Louis University, November 28, 1990.
13. Andrus CH: Biliary tract and pancreatic duct emergencies. Emergency Department Grand Rounds, Saint Louis University, December 11, 1990.
14. Andrus CH, Andrus PB, Daake C: Stress ulcers in critically ill patients. Annual Meeting of the Greater St. Louis Chapter of the American Association of Critical Care Nurses, St. Louis, MO, March 15, 1991.
15. Andrus CH, Vernava AM: Laparoscopy: Are there any indications in colorectal disease? "Management of colon and rectal disease in 1991: An update for the practitioner, specialist, and surgeon," Saint Louis University, April 20, 1991.
16. Andrus CH, Soper N: Laparoscopic surgery: Point/counterpoint. Surgical Grand Rounds at Saint Louis University, September 28, 1991.
17. Andrus CH: Endoscopic ultrasonography. Annual meeting of GSGNA (Gateway Society of Gastroenterology, Nurses and Associates) at Christian Northeast Hospital, St. Louis, MO, October 26, 1991.
18. Andrus CH, Fleshman J, Vernava AM, Wexner S: Laparoscopic colectomy: The future is here? "Management of challenging problems in colon and rectal disease in 1992: An update for the clinician," Saint Louis University, April 25, 1992.
19. Andrus CH: An overview of laparoscopic surgery. Founders Week Scientific Program-- Medical Alumni, Saint Louis University, October 23, 1992.

20. Andrus CH: What is new in laparoscopy? General Grand Rounds, Saint Elizabeth's Hospital, Belleville, IL, October 27, 1992.
21. Andrus CH: What's new in laparoscopy? Monthly meeting of the St. Louis Chapter of the Occupational Health Nurses Association, Westport Plaza, St. Louis, MO, January 28, 1993.
22. Andrus CH: Dietary modification in the treatment of inborn errors in metabolism. Freshman medical student nutrition course, Saint Louis University Medical School, April 22, 1993.
23. Andrus Charles Hiram and Andrus Charles Harold: Clinical Case Study: Dietary modifications in the treatment of childhood epilepsy. Freshman medical student nutrition course, Saint Louis University Medical School, April 22, 1993, April 19, 1994, April, 1995, & April 4, 1996.
24. Andrus CH: An infectious cause of peptic ulcer disease: *Helicobacter pylori*. Weekly Transplant Grand Rounds, Saint Louis University Hospital, May 26, 1993.
25. Andrus CH: Endoscopic assessment of ischemic colitis. Surgery/Gastroenterology Combined Rounds, Saint Louis University Hospital, June 2, 1993.
26. Andrus CH: Hepatic failure. St. Louis VAMC Critical Care Course for Nurses. John Cochran VAMC, St. Louis, MO, September 3, 1993, September 22, 1995, November 17, 1995, February 16, 1996.
27. Andrus CH: Indications for upper endoscopy. SAGES Endoscopy Workshop for Surgical Residents. Ethicon Endo-Surgery Institute, Cincinnati, Ohio, January 21-22, 1994, January 13-14, 1995.
28. Andrus CH: Physiologic effects of pneumoperitoneum. St. John's Mercy Medical Center, August 10, 1994.
29. Andrus CH: The Abdomen and Nutrition. Practical Anatomy and Surgical Technique Workshop of St. Louis, November 9, 1994.
30. Andrus CH: Health Options for Teens. Saint Louis University Hospital in conjunction with the American Lung Association. St. Louis, MO, July 11, 1995.
31. Andrus CH: The Acute Abdomen. Internal Medicine Resident Conference. Saint Louis University Medical Center. July 20, 1995.
32. Andrus CH: What's new in laparoscopy? Grand Rounds, Saint Louis University Medical Center, January 27, 1996.
33. Andrus CH: Physiological changes during laparoscopy. Grand Rounds, Saint Louis University Medical Center, February 28, 1996.
34. Andrus CH: The indications of upper endoscopy and the therapeutic maneuvers in esophageal stricture disease and peptic ulcer disease. M&M Group I (Blue, Vascular, VAH, C/R), Saint Louis University Medical Center, April 10, 1996.
35. Andrus CH: Ethicon endosurgery resident laparoscopic training program. Saint Louis University Medical Center, June 21-22, 1996.



36. Andrus CH: Molecular biology in this era of managed care. Department of Surgery Grand Rounds, Loyola University Medical School, October 19, 1996.
37. As the former President-elect of the St. Louis Surgical Society, I coordinated the St. Louis Surgical Society's Fall Panel of November 5, 1996, on: "Molecular Medicine and the Practicing Surgeon" which included the discussants: Robert Smith, M.D., Ph.D., Professor of Medicine, Joslin Diabetic Clinic, Harvard University: "An Overview of Molecular Biology and its Influences on Clinical Practice"; Diane Radford, M.D., F.A.C.S., Assistant Professor of Surgery, Washington University School of Medicine: "Genetic Screening in Breast Malignancies"; Charles Andrus, M.D., F.A.C.S.: "Molecular Biology and Managed Care"; and Kevin O'Rourke, O.P., J.C.D., Saint Louis University School of Medicine: "The Ethical Implications of Molecular Biological Diagnoses and Therapy."
38. Andrus CH: What's new in laparoscopy. Department of Surgery Grand Rounds, Loyola University Medical School, January 11, 1997.
39. Andrus CH: What's new in laparoscopy. GI Service Conference, Edward Hines, Jr. VAH, May 21, 1997.
40. Andrus CH: As a Chemistry major, you want to be a doctor? Loyola University Chapter of the American Chemical Society, Loyola University, Lakeshore Campus, November 30, 1999.
41. Andrus CH: Laparoscopic staging of pancreatic cancer. Tumor Board conference: "The Role of Imaging in the Staging of Pancreatic Cancer." Loyola University Medical Center, April 11, 2001.
42. Andrus CH: Medical Implications of MVAs. To the Driver Education Classes of St. Mary's High School, Stockton, CA. November 6, 2002.
43. Andrus CH: Transfusion therapy. Surgery Residents, San Joaquin General Hospital, January, 2003.
44. Andrus CH: Transfusion therapy. Combined Pathologic Conference (Departments of Family Practice, Internal Medicine, & Surgery), San Joaquin General Hospital, July 30, 2003.
45. Andrus CH: Presentation to SJGH Surgical Grand Rounds: S A F E R: Sleep, Alertness, and Fatigue Education in Residency, September 24, 2003.
46. Andrus CH: MVAs: The Silent Epidemic of Youthful Drivers. The presentation by the Medical Director, Trauma Services, SSM DePaul Health Center, on the two day MADD-sponsored docudrama. Ritenour High School, St. John, MO, May 6, 2005.
47. Andrus CH: Trauma and the Pregnant Patient. Lecture Series for Emergency Medical Services, St. Louis County Fire Districts, as co-Director, EMS Services, SSM DePaul Health Center, St. Louis, MO June 1-3, 2005. 6 presentations x 2 hrs = 12 hours of presentations.
48. Andrus CH, Scodary D: Head Trauma. Lecture Series for Emergency Medical Services, St. Louis County Fire Districts, as co-Director, EMS Services, SSM DePaul Health Center, St. Louis, MO September 20-22, 2005. 6 presentations x 2 hrs = 12 hours of presentations.

49. Andrus CH: Trauma Classification and EMS/ED Communications Lecture Series for Emergency Medical Services, St. Louis County Fire Districts, as co-Director, EMS Services, SSM DePaul Health Center, St. Louis, MO November 16-18, 2005. 9 presentations x 2 hrs = 18 hours of presentations.
50. Andrus CH: From the Accident Scene to the ED via the Back Board. Lecture Series for Emergency Medical Services, St. Louis County Fire Districts, as co-Director, EMS Services, SSM DePaul Health Center, St. Louis, MO March 7-9, 2006. 9 presentations x 2 hrs = 18 hours of presentations.
51. Andrus CH: Combating a Major Killer. Presentation in conjunction with DocuDrama at Pattonville High School on Drunk Driving, April 12, 2006.
52. Andrus CH: Abdominal Trauma: The Silent Killer. Lecture Series for Emergency Medical Services, St. Louis County Fire Districts, as co-Director, EMS Services, SSM DePaul Health Center, St. Louis, MO April 18-20, 2006. 9 presentations x 2 hrs = 18 hours of presentations.
53. Andrus CH, O'Connor M: Impediments to the Delivery of Trauma Care at SSM DePaul Health Center. Presented before the public portion of the SSM DePaul Health Center Trauma Peer Review Committee, June 12, 2006.
54. Andrus CH: Acute abdomen and appendicitis. Junior medical student lectures every cycle. Department of Surgery, Saint Louis University School of Medicine.
55. Andrus CH: Hernia. Junior medical student lectures every cycle. Department of Surgery, Saint Louis University School of Medicine.
56. Andrus CH: Small bowel obstruction. Junior medical student lectures every cycle. Department of Surgery, Saint Louis University School of Medicine.
57. Andrus CH: Accountability, AMDG, Surgical Education, and One Surgeon's View. Surgery Grand Rounds, Saint Louis University School of Medicine, October 18, 2006.
58. Andrus CH: To Err is Human-Surgical Self-Reflection as a Tradition: The M&M Conference. Surgery Grand Rounds, Saint Louis University School of Medicine, March 28, 2007.
59. Andrus CH: Appendicitis, Acute Abdomen, Small Bowel Obstruction, and Hernias. Lecturer to the junior class of every junior student surgery rotation - six to eight times a year.
60. Andrus CH: Andrus PB, Andrus CH, Andrus PC, Andrus TM, Andrus MF, Andrus TS: The Story of a Mitochondrial Cytopathy - A Case Study in Molecular Biology. Freshman Molecule Biology Course, Saint Louis University School of Medicine, October 30, 2007.
61. Andrus CH: Mitochondrial Cytopathies: *Mysteries Wrapped in Enigmas* - One Family's Experience, St. Louis University Pediatric Grand Rounds, SSM Cardinal Glennon Children's Medical Center, September 24, 2008; St. Louis University Surgery Grand Rounds, Saint Louis University School of Medicine, October 1, 2008; and St. Louis University Obstetrics & Gynecology Grand Rounds, SSM St. Mary's Health Center, October 3, 2008.

62. Andrus CH: Pediatric Trauma, State of Illinois Trauma Nurse Specialist Program, St. Louis University Hospital, February 20, 2009 and March 13, 2009.
63. Andrus CH: The Surgery Resident On-Call: A Potpourri of Perioperative Care and Challenges. St. Louis University Surgery Grand Rounds, Saint Louis University School of Medicine, March 25, 2009.
64. Andrus CH: The PIF. Saint Louis University Surgery Grand Rounds, St. Louis University School of Medicine, June 3, 2009.
65. Andrus CH: 2009 - 2010 Resident Orientation. Department of Surgery, Saint Louis University School of Medicine, June 30, 2009.
66. Andrus CH: Surgery Residency in 2009. Saint Louis University Surgery Grand Rounds, St. Louis University School of Medicine, June 24, 2009.
67. Andrus CH: Stress, Fatigue, and the IOM report: *Resident Duty Hours Enhancing Sleep, Supervision, and Safety*. Saint Louis University Surgery Grand Rounds, St. Louis University School of Medicine, August 5, 2009.
68. Andrus CH: Basic Science: The Adrenal Gland Anatomy, physiology, and syndromes / functional pathology. Saint Louis University Surgery Grand Rounds, Saint Louis University School of Medicine, September 2, 2009.
69. Andrus CH: The Changing Facets of Postgraduate Surgical Education. Saint Louis University Surgery Grand Rounds, Saint Louis University School of Medicine, September 16, 2009.
70. Klinkner DB, Andrus CH: Basic Science: Adrenal Gland II--Pathologic Conditions, Operations, and Chemical Therapies, Saint Louis University Surgery Grand Rounds, St. Louis University School of Medicine, September 23, 2009.
71. Andrus CH: Junior Student Lectures, Department of Surgery, Saint Louis University School of Medicine, October 1, 2009.
72. Andrus CH and other Trauma Surgery Faculty: "Trauma Jeopardy", Department of Surgery Grand Rounds, December 16, 2013.
73. Andrus CH: Instructor, ATLS Course, Course #35374-P, Saint Louis University Hospital, January 22, 2010.
74. Andrus CH: Junior Student Lectures, Department of Surgery, Saint Louis University School of Medicine, January 28, 2010.
75. Andrus CH: Surgical Residency: Roles, Responsibilities, and Relationships, Department of Surgery Grand Rounds, Saint Louis University School of Medicine, February 3, 2010.
76. Andrus CH: Fluid and Electrolytes, Senior Student Capstone Lectures, Saint Louis University School of Medicine, March 24, 2010.
77. Andrus CH: Junior Student Lectures, Department of Surgery, Saint Louis University School of Medicine, March 25, 2010.
78. Andrus CH: Junior Lectures, Department of Surgery, Saint Louis University School of Medicine, June 3, 2010.

79. Andrus CH: Course Director, ATLS Course #35375-P for Surgery Interns, Department of Surgery, Saint Louis University School of Medicine, June 26, 2010.
80. Andrus CH: "The Surgery Residency at Saint Louis University, (2010) Including the S.A.F.E.R. lecture for 2010-2011 Part of the 2010 Resident Orientation Symposia", Department of Surgery Grand Rounds, Saint Louis University School of Medicine, June 30, 2010.
81. Andrus CH: "Resident Procedural Skills Simulation Center", Department of Surgery Grand Rounds, Saint Louis University School of Medicine, July 7, 2010.
82. Andrus CH: Junior Student Lectures, Department of Surgery, Saint Louis University School of Medicine, September 23, 2010.
83. Andrus CH, Hopping J, Hiler AM: "Common Bile Duct Stones in 2010" Case Presentation and Panel Discussion, Department of Surgery Grand Rounds, Saint Louis University School of Medicine, September 29, 2010.
84. Andrus CH: "Conducting an M&M Conference", Joint Grand Rounds of the Department of Surgery and Anesthesiology, Saint Louis University School of Medicine, October 6, 2010.
85. Andrus CH: Instructor, "Pediatric Trauma Module", Pediatric Advanced Life Support (PALS), SSM Cardinal Glennon Children's Hospital, October 12, 2010.
86. Andrus CH: Junior Lectures, Department of Surgery, Saint Louis University School of Medicine, December 2, 2010.
87. Andrus CH: Instructor, ATLS Course, Course #35256-P/SR, Saint Louis University Hospital, January 21, 2011.
88. Andrus CH: Junior Student Lectures, Department of Surgery, Saint Louis University School of Medicine, February 10, 2011.
89. Hacker S, Andrus CH: "Trauma and the Pregnant Patient", Emergency Medicine Grand Rounds, Department of Surgery, Saint Louis University School of Medicine, February 15, 2011.
90. Andrus CH: Instructor, "Pediatric Trauma Module", Pediatric Advanced Life Support (PALS), SSM Cardinal Glennon Children's Hospital, March 15, 2011.
91. Andrus CH: "Report on the Recent Meeting of the Association of Program Directors in Surgery (APDS) and New Regulations for Residency Programs", Department of Surgery Grand Rounds, Saint Louis University School of Medicine, April 26, 2011.
92. Andrus CH: Junior Student Lectures, Department of Surgery, Saint Louis University School of Medicine, May 26, 2011.
93. Andrus CH: Surgery Resident Orientation, Department of Surgery, Saint Louis University School of Medicine, June 27, 2011.
94. Andrus CH: Course Director, ATLS Course #38216-P/SR for Surgery Interns, Department of Surgery, Saint Louis University School of Medicine, June 28-29, 2011.

95. Andrus CH: "The Functioning of the Surgery Residency at Saint Louis University, 2011", St. Louis University Surgery Grand Rounds, Saint Louis University School of Medicine, June 29, 2011.
96. Andrus CH: "Resident Procedural Skills Simulation Center", Department of Surgery Grand Rounds, Saint Louis University School of Medicine, July 6, 2011.
97. Andrus CH: "The History of Surgical Training", Department of Surgery Grand Rounds, Saint Louis University School of Medicine, July 13, 2011.
98. Andrus CH: "The S.A.F.E.R. Lecture for 2011-2012", Department of Surgery Grand Rounds, Saint Louis University School of Medicine, August 3, 2011.
99. Andrus CH: Junior Student Lectures, Department of Surgery, Saint Louis University School of Medicine, August 4, 2011.
100. Andrus CH, Antal M: "ACGME General Competencies: Practice Based Learning and Systems Based Practice", St. Louis University Surgery Grand Rounds, Saint Louis University School of Medicine, August 10, 2011.
101. Andrus CH: Junior Student Lectures, Department of Surgery, Saint Louis University School of Medicine, August 11, 2011.
102. Andrus CH: "The Acute Infected Abdomen (Peritonitis)", St. Louis University Surgery Grand Rounds, Saint Louis University School of Medicine, September 14, 2011.
103. Andrus CH: Instructor, ATLS Course, Course #39485-I, Saint Louis University Hospital, January 9, 2012.
104. Andrus CH: Junior Student Lectures, Department of Surgery, Saint Louis University School of Medicine, January 26, 2012.
105. Andrus CH: "Update and Analysis of the Anonymous Resident Survey with Follow-up of the General Surgery Resident Committees of SLUSOM Of October 12, 2011", St. Louis University Surgery Grand Rounds, Saint Louis University School of Medicine, February 1, 2012.
106. Andrus CH: Junior Student Lectures, Department of Surgery, Saint Louis University School of Medicine, February 9, 2012.
107. Andrus CH: "Trauma in the Adult Women", Trauma Nurse Specialist (TNS) Course, Saint Louis University Hospital, February 10, 2012.
108. Andrus CH: Junior Student Lectures, Department of Surgery, Saint Louis University School of Medicine, March 22, 2012.
109. Andrus CH: Junior Student Lectures, Department of Surgery, Saint Louis University School of Medicine, May 10, 2012.
110. Andrus CH: Junior Student Lectures, Department of Surgery, Saint Louis University School of Medicine, May 24, 2012.
111. Andrus CH: "The Functioning of the Surgery Residency at Saint Louis University, 2011", St. Louis University Surgery Grand Rounds, Saint Louis University School of Medicine, June 27, 2012.

112. Andrus CH: Course Director, ATLS Course for Surgery Interns, Department of Surgery, Saint Louis University School of Medicine, June 28-29, 2012.
113. Andrus CH: "Resident Procedural Skills Simulation Center", Department of Surgery Grand Rounds, Saint Louis University School of Medicine, July 11, 2012.
114. Andrus CH, Antal M: "ACGME General Competencies: Practice Based Learning and Systems Based Practice", St. Louis University Surgery Grand Rounds, Saint Louis University School of Medicine, August 1, 2012.
115. Andrus CH: Junior Student Lectures, Department of Surgery, Saint Louis University School of Medicine, August 2, 2012.
116. Andrus CH: "The S.A.F.E.R. Lecture for 2012-2013", Department of Surgery Grand Rounds, Saint Louis University School of Medicine, August 8, 2012.
117. Andrus CH: Junior Student Lectures, Department of Surgery, Saint Louis University School of Medicine, August 23, 2012.
118. Andrus CH: "The History of Surgical Training", Department of Surgery Grand Rounds, Saint Louis University School of Medicine, August 29, 2012.
119. Andrus CH: Junior Student Lectures, Department of Surgery, Saint Louis University School of Medicine, September 13, 2012.
120. Andrus CH: Junior Student Lectures, Department of Surgery, Saint Louis University School of Medicine, October 11, 2012.
121. Andrus CH: Instructor, "Pediatric Trauma Resuscitation Module", Pediatric Advanced Life Support (PALS), SSM Cardinal Glennon Children's Hospital, October 23, 2012.
122. Andrus CH: Junior Student Lectures, Department of Surgery, Saint Louis University School of Medicine, November 8, 2012.
123. Andrus CH: Junior Student Lectures, Department of Surgery, Saint Louis University School of Medicine, November 29, 2012.
124. Andrus CH: "Kinematics of Trauma Lecture", Trauma Nurse Specialist (TNS) Course, Saint Louis University Hospital, January 25, 2013.
125. Andrus CH: "Blood Banking for the Surgeon", Department of Surgery Grand Rounds, Saint Louis University School of Medicine, February 6, 2013.
126. Andrus CH: "Kinematics of Trauma" (Basic Science Lecture), Saint Louis University Surgery Grand Rounds, Saint Louis University School of Medicine, February 13, 2013.
127. Andrus CH: Junior Student Lectures, Department of Surgery, Saint Louis University School of Medicine, February 14, 2013.
128. Andrus CH: "Fluid and Electrolytes", Senior Student Capstone Lectures, Saint Louis University School of Medicine, March 20, 2013.
129. Andrus CH: "Blood Banking and Surgical Nutrition", Senior Student Capstone Lectures, Saint Louis University School of Medicine, March 21, 2013.

130. Andrus CH: Junior Student Lectures, Department of Surgery, Saint Louis University School of Medicine, April 4, 2013.
131. Andrus CH: Mock Orals of Senior Surgery Residents, Combined Departments of Surgery, Saint Louis University School of Medicine and Washington University School of Medicine, April 10, 2013.
132. Andrus CH: Junior Student Lectures, Department of Surgery, Saint Louis University School of Medicine, May 16, 2013.
133. Andrus CH: "Resident Surgical Skills and Laparoscopic Lab for incoming Surgery Interns", Department of Surgery, Saint Louis University School of Medicine, June 24, 2013.
134. Andrus CH: "Resident Research Orientation for incoming Surgery Interns", Department of Surgery, Saint Louis University School of Medicine, June 24, 2013.
135. Andrus CH: "Fluid and Electrolytes, TPN, and Blood Component Therapy for incoming Surgery Interns", Department of Surgery, Saint Louis University School of Medicine, July 10, 2013.
136. Andrus CH, Antal M: "ACGME General Competencies: Practice Based Learning and Systems Based Practice", St. Louis University Surgery Grand Rounds, Saint Louis University School of Medicine, July 31, 2013.
137. Andrus CH: Junior Student Lectures, Department of Surgery, Saint Louis University School of Medicine, August 1, 2013.
138. Andrus CH: "The S.A.F.E.R. Lecture for 2013-2014", Department of Surgery Grand Rounds, Saint Louis University School of Medicine, August 14, 2013.
139. McMellen M: "ABSITE review of Head and Neck", Andrus CH (mentor), Saint Louis University Surgery Grand Rounds, Saint Louis University School of Medicine, July 31, 2013.
140. Andrus CH: "Anterior Abdominal Wall, Inguinal Region, and Hernias", Freshman Medical Student Anatomy Course—Clinical Correlation, Saint Louis University School of Medicine, November 6, 2013.
141. Andrus CH: "Gastrointestinal System", Freshman Medical Student Anatomy Course—Clinical Correlation, Saint Louis University School of Medicine, November 7, 2013.
142. Andrus CH: Resident Skills Lab and also lecture on: Fluid, electrolytes, and how and why to write IV fluid orders, blood, and TPN. Lecture before new PGY-1 residents. SLUSOM, July 9, 2014
143. Andrus CH: Surgical Grand Rounds: ACGME General Competencies: Practice-based learning and Systems-based Practice (ACS NSQIP), SLUSOM, July 23, 2014.
144. Andrus CH: Surgical Grand Rounds: S.A.F.E.R. lecture, SLUSOM, Aug 13, 2014.
145. Andrus CH: Kinematics of Trauma. TNS Course (Trauma Nurse Specialist Course). SLUSOM, September 19, 2014.



146. Andrus CH: Appendicitis, Cholecystitis, and Biliary System, Junior Lecture, SLUSOM, January 15, 2015.
147. Andrus CH: Kinematics of Trauma. TNS Course (Trauma Nurse Specialist Course). SLUSOM, January 16, 2015.
148. Andrus CH: Lecture to junior medical students the first Monday of each 8-week rotation, Fluid and electrolyte lecture, SLUSOM, AY 2014-2015.
149. Andrus CH: Instructor of ATLS lectures and case scenarios, March 7, 2015.
150. Andrus CH: Capstone lecture to senior medical students, Fluid and electrolyte lecture, SLUSOM, March 12, 2015.
151. Andrus CH: Kinematics of Trauma. Department of Anesthesiology Grand Rounds, SLUSOM, May 13, 2015.
152. Participated as a General Surgery faculty member in the combined Washington University/SLUSOM Surgery Mock Orals, WUSOM, May 13, 2015.
153. Andrus CH: Faculty Judge of the ACS-MO Chapter Podium Sessions, Councilor, and Newly-elected Vice-President of the ACS-MO Chapter, Annual Meeting of the ACS-MO Chapter, Lake of the Ozarks, May 28-31, 2015.
154. Andrus CH: Research Opportunities at General Surgery Orientation in morning session and suture and instrument afternoon session, June 22, 2015.
155. Patel, Andrus CH: CVC lecture (Patel) and SIMS lab on CVC, chest tube placement, and foley placement for interns, July 8, 2015.
156. Andrus CH: Fluid, electrolytes, TPN, and blood component therapy lecture fore the interns, July 8, 2015.
157. Andrus CH: Surgical Grand Rounds: *Practice-based learning and systems-based practice*. July 15, 2015.
158. Andrus CH: Surgical Grand Rounds: S.A.F.E.R. lecturer. August 26, 2015.
159. Andrus CH: Anesthesiology Grand Rounds: A Surgeon's View of Blood Banking, December 2, 2015.
160. Andrus CH: Lecture to junior medical students the first Monday of each 8-week rotation, Fluid and electrolyte lecture, SLUSOM, AY 2015-2016.
161. Andrus CH: Capstone lecture to senior medical students, Fluid and electrolyte lecture, SLUSOM, March 12, 2016.
162. Participated as a General Surgery faculty member in the combined Washington University/SLUSOM Surgery Mock Orals, SLUSOM, May 5, 2016.
163. Andrus CH: PALS Trauma lecture and afternoon case scenario, June 23, 2016.
164. Andrus CH: Research Opportunities at General Surgery Orientation in morning session and suture and instrument afternoon session, June 27, 2016.

165. Patel, Andrus CH: CVC lecture (Patel) and SIMS lab on CVC, chest tube placement, and Foley placement for interns, July 13, 2016.
166. Andrus CH: Surgical Grand Rounds: *Practice-based learning and systems-based practice*. August 24, 2016.
167. Andrus CH (moderator): Small group SCORE/True Learn Question Review: Inguinal and Femoral Hernias, Ventral Hernias, MIS Principles, September 14, 2016.
168. Andrus CH (moderator): Small group Mock Orals: Inguinal and Femoral Hernias, Ventral Hernias, MIS Principles, September 21, 2016.
169. Andrus CH (moderator): Small group SCORE/True Learn Question Review: Benign biliary 1 & 2, October 5, 2016.
170. Andrus CH (moderator): Small group Mock Orals: Benign biliary 1 & 2, October 12, 2016.
171. Andrus CH: Junior Medical Student lecture on Fluids, Electrolytes, Blood Components, and TPN: 8/29/2016, 10/25/2016.
172. Charles Andrus, M. D. and Catherine Wittgen, M.D., Co-chairpersons, weekly Surgery Grand Rounds and M&M conference
173. Andrus CH: Moderator, SCORE on first Wednesday of the month and Mock Orals for SLU residents the second Wednesday of the month: 9/14/2016, 9/21/2016; 10/5/2016, 10/12/2016; 11/9/2017, 11/16/2016; 12/14/2017; 2/1/2017, 2/8/2017; 3/1/2017, 3/8/2017; 4/5/2017, 4/12/2017.
174. Andrus CH: Surgery Intern Orientation: Procedures (Central lines, intubation, chest tubes) and the lecture on Fluids, Electrolytes, Blood component therapy, and TPN, Wednesday morning (~4 hours), 7/13/2016.
175. Andrus CH: The Core Competencies of Practice-Based Learning and Systems Based Practice, Grand Rounds, 8/24/2016.
176. Andrus CH: Senior Medical Student Capstone on Fluids, Electrolytes, Blood Component Therapy, 3/13/2017.
177. Washington U-SLU city-wide General Surgery Resident Mock Orals (8 hours at Washington University), 4/26/2017.
178. Andrus CH: The Core Competencies of Practice-Based Learning and Systems Based Practice, Grand Rounds, 7/19/2017.
179. Andrus CH: Surgery Intern Orientation: Procedures (Central lines, intubation, chest tubes) and the lecture on Fluids, Electrolytes, Blood component therapy, and TPN, Wednesday morning (~4 hours), 7/12/2017.
180. Andrus CH: Grand Rounds—Cholelithiasis + Epigastric Pain does not equal laparoscopic cholecystectomy—A surgeons study of H. pylori. Surgical Grand Rounds, Saint Louis University SOM, Department of Surgery, 1/31/2018.
181. Andrus CH: Kinematics of Trauma. TNS Course (Trauma Nurse Specialist Course). SLUSOM, February 23, 2018.

182. Andrus CH: Capstone lecture to senior medical students, Fluid and electrolyte lecture, TPN, and blood component therapy, SLUSOM, March 7, 2018.
183. Andrus CH: Wednesday small resident question review: "General Surgery topics in Thoracic Surgery", 4/11/2018.
184. Andrus CH: Wednesday small resident mock orals: "General Surgery topics in Thoracic Surgery", 4/18/2018.
185. Washington U-SLU city-wide General Surgery Resident Mock Orals (8 hours at St. Louis University), 5/9/2018.
186. Andrus CH: Extremes of Age lecture for ATLS, ATLS 2-day course for surgery residents, St. Louis University LRC, 6/28/2018.
187. Andrus CH: Faculty discussant for M&M conference. Surgery Intern Orientation: Procedures (Central lines, intubation, chest tubes) and the lecture on Fluids, Electrolytes, Blood component therapy, and TPN, Wednesday morning (~5 hours), 7/18/2018.
188. Andrus CH: Physician Vesting in One's Patients -- The Core Competencies of Practice-Based Learning and Systems Based Practice, Grand Rounds, 7/25/2018.
189. Andrus CH: Inguinal hernia repair in the 21<sup>st</sup> century. Department of Surgery Grand Rounds, Saint Louis University School of Medicine, 10/30/2019.

**M. Supplemental Material:**

**I. Presentations (national and international meetings), seminars**

1. Vernava AM, Andrus CH, Herrmann VM, Kaminski DL: Splenectomy for hematologic disease in adults. Presented as a poster at the Southwestern Surgical Congress in May, 1987, by A. Vernava.
2. Westfall SH, Andrus CH, Naunheim KS: A reproducible, safe jejunostomy replacement technique by a percutaneous endoscopic method. Presented at the annual SAGES meeting, April, 1989, by C. Andrus.
3. Rosato RM, Andrus CH: The effect of postoperative epidural analgesia on the duration of ileus in abdominal surgery. Presented at the Missouri Chapter of the American College of Surgeons, June, 1989, by R. Rosato.
4. Andrus CH, Dean PA, Ponsky JL: Evaluation of safe, effective intravenous sedation for utilization in endoscopic procedures. Presented as a poster at the World Congress of Surgical Endoscopy, March 15-17, 1990, Atlanta, GA, by C. Andrus.
5. German DS, Andrus CH: A simplified, reproducible, inexpensive method of compartmental pressure monitoring. Presented as a poster at the Southwestern Surgical Congress, April 22-25, 1990, LaQuinta, CA, by D. German.
6. Rosato RM, Andrus CH: The effect of postoperative epidural analgesia on the duration of ileus in abdominal surgery. Presented as a poster at the Southwestern Surgical Congress, April 22-25, 1990, LaQuinta, CA, by R. Rosato.
7. Andrus CH: Endoscopic ultrasonography: A new, highly sensitive and specific diagnostic and staging technique for upper gastrointestinal tumors. *Oncology News - Saint Louis University Medical Center*, 4:1, 4, 1990.
8. Vernava AM, Beckman RF, Andrus CH, Johnson FE, Herrmann VM, Kaminski DL: Tangential colostomy preferred for temporary fecal diversion. Presented as a poster at the American Society of Colon and Rectal Surgeons, April 19 - May 4, 1990, St. Louis, MO, by A. Vernava.
9. Andrus CH, Daly JL: Utilization of an in-house generated quality assurance database for the evaluation of the surgical services in a large university-affiliated VA hospital. Presented at the Surgical Section of the Southern Medical Association, October 16, 1990, by C. Andrus.
10. Wittgen CM, Andrus CH, Fitzgerald SD, Baudendistel LJ, Dahms TE, Kaminski DL: Analysis of hemodynamic and ventilatory effects of laparoscopic cholecystectomy. Presented at the annual meeting of the Western Surgical Association, Scottsdale, AZ, November 14, 1990.
11. Andrus CH, Blatner ME, Wittgen CM, Kaminski DL: Cystic duct cholangiography during laparoscopic cholecystectomy. Presented at the Scientific Session of the Annual Business Meeting of the St. Louis Surgical Society, January 15, 1991.
12. Schneider TA, Andrus CH: The efficacy of endoscopic Congo red confirmation of completeness of proximal gastric vagotomy: An essential procedure. Pre-presented as a poster at the Annual Scientific Session of SAGES, Monterey, CA, April 17-19, 1991. (Won third prize out of 47 posters).

13. Fitzgerald SD, Bailey PV, Liebscher GJ, Andrus CH: Laparoscopic cholecystectomy in anticoagulated patients. Presented as a poster at the Annual Scientific Session of SAGES, Monterey, CA, April 17-19, 1991.
14. Zegula HD, Esterl RM, Andrus CH, Wade TP: Anastomotic leak: A review of risk factors and methods of diagnosis and surgical treatment. Presented as a case report podium presentation at the Southwestern Surgical Congress, Las Vegas, NV, April 24, 1991.
15. Mehan DJ, Hagood P, Andrus CH, Parra R: Laparoscopic ligation of internal spermatic veins. A new surgical approach to the correction of varicoceles. (Video). Ninth World Congress on Endourology and ESWC, Vienna, Austria, June 20 & 22, 1991.
16. Naunheim KS, Petruska PJ, Roy T, Andrus CH, Johnson FE, Schlueter JM, Baue AE: Preoperative chemoradiation for esophageal carcinoma. Western Thoracic Surgical Association, Seattle, WA, June 28, 1991.
17. Wittgen CM, Andrus JP, Andrus CH, Kaminski DL: Cholecystectomy in the debilitated patient: Which procedure is best? 1991 Annual Professional Meeting of the Missouri Chapter of ACS, Lake of the Ozarks, MO, June 30, 1991.
18. Mehan DJ, Hagood P, Andrus C, Parra R: Laparoscopic ligation of internal spermatic vein. A new surgical approach to the correction of varicocele. 1991 Annual Professional Meeting of the Missouri Chapter of ACS, Lake of the Ozarks, MO, June 30, 1991.
19. Schneider TA, Andrus CH: The efficacy of endoscopic Congo red confirmation of completeness of proximal gastric vagotomy: An essential procedure. 1991 Annual Professional Meeting of the Missouri Chapter of the ACS, Lake of the Ozarks, MO, June 29, 1991.
20. Andrus CH, Daly JL, Johnson FE, Wade TP, Kraybill WG, and Moley JF: Continuing evaluation and utilization of a VA Hospital in-house generated quality assurance surgical database. Presented to the Clinical Indicator Symposium, Department of Veteran's Affairs, August 26-29, 1991, Adam's Mark Hotel, St. Louis, MO.
21. Mehan DJ, Parra RO, Hagood PG, and Andrus C: Laparoscopic ligation of internal spermatic vein: A new surgical approach to the correction of varicocele. Presented at the 70th Annual Meeting of the South Central Section of the American Urological Association, November 17, 1991.
22. Parra RO, Andrus CH, Boullier JA: Staging laparoscopic pelvic lymph node dissection for adenocarcinoma of the prostate: Experience and indications. Presented at the Society of Surgical Oncology 1992 Annual Meeting, The Waldorf Astoria Hotel, New York, NY.
23. Schneider TA, Wittgen CM, Andrus CH, Kaminski DL: Comparison of minimally invasive methods of parietal cell vagotomy in a porcine model. Central Surgical Association, March 5, 1992.
24. Andrus CH, Wittgen CM, Naunheim KS, McManama GP, Rinehart GC, Clarkston WK, Wade TP: Densitometric evaluation of endoscopic ultrasonography. Poster presentation, ASGE, May 12, 1992.
25. Schneider TA, LaRegina MC, Fitzgerald SD, Wittgen CM, Virgo KS, Kaminski DL, Andrus CH: Confirmation of parietal cell distribution by histologic and Congo red techniques in a porcine model. Poster presentation, AGA, May 12, 1992.

26. Schneider TA, Wittgen CM, Andrus CH, Kaminski DL: Comparison of minimally invasive methods of parietal cell vagotomy in a porcine model. Missouri Chapter, American College of Surgeons, June 20, 1992.
27. Carr SC, Marts BC, Andrus CH, Kaminski DL, Wade TP: Staged surgical management of cholecystocutaneous abscesses. Presented as a poster to the Missouri Chapter, American College of Surgeons, June 20, 1992.
28. Wittgen CM, Andrus JP, Andrus CH, Kaminski DL: Cholecystectomy: Which procedure is best for the high risk patient? Presented as a podium presentation - SAGES, Washington, DC, April 11, 1992, and the Third World Congress of Endoscopic Surgery, Bordeaux, France, June 18, 1992.
29. Mehan DJ, Andrus C, Parra O: Laparoscopic varicocelectomy [videorecording]/ report of a new technique to correct male infertility: Saint Louis University Medical Center. American College of Surgeons. Film Library. Woodbury, CT: Cine-Med,[1992], NLM 9414407, NLM Call Number WJ 780 VC no. 11 1992.
30. Neuberger TJ, Wittgen CM, Schneider TA, Andrus CH, Panneton WM, Kaminski DL: Evaluation of alternative PGV techniques in a chronic rat model. Poster presentation at Digestive Disease Week, ASGE Poster session, May 18, 1993.
31. Wittgen CM, Schneider TA, Fitzgerald SD, Panneton WM, La Regina MC, Johnson S, Kaminski DL, Andrus CH: Proximal gastric vagotomy by minimally invasive methods in an acute rat model. Podium presentation at the American College of Surgeons - Missouri Chapter, June 20, 1993. (Dr. Wittgen won the 1st place resident's award for the presentation).
32. Schneider TA, La Regina MC, Fitzgerald SD, Wittgen CM, Virgo KS, Kaminski DL, Andrus CH: Confirmation of parietal cell vagotomy in a porcine model. Podium presentation, VA Surgeons, Augusta, Georgia, May 1, 1993.
33. Andrus CH: Laparoscopic cholecystectomy and physiologic changes. Department of Anesthesiology faculty, residents and nurses. Wednesday, November 30, 1994. Saint Louis University Medical Center, St. Louis, MO.
34. Esterl RM: Practical Pearls in Surgery: Gastrostomy tube obstruction. Contemporary Surgery 45 (6); Dec, 1994: 341.
35. Andrus CH: Endoscopy in the peptic ulcer patient. SAGES Flexible GI Endoscopy 1995, SAGES Annual Meeting, Orlando, Florida, March 11, 1995.
36. Andrus CH: Endoscopic approach to esophageal strictures. SAGES Flexible Endoscopy 1995, SAGES Annual Meeting, Orlando, Florida, March 11, 1995.
37. Andrus CH: "C.O.P.D.," Panel IV: Special problems in laparoscopy. SAGES Annual Meeting, Orlando, Florida, March 14, 1995.
38. Andrus CH: "New things in laparoscopy." Saint Louis University CME Outreach Program, March 25, 1995.
39. Andrus CH: The laparoscopic approach to the spine. Spinal Fracture Fixation, Practical Anatomy and Surgical Technique Workshop, St. Louis, MO, May 1-5, 1995.

40. Andrus C, et al: Evaluation of new methods of proximal gastric vagotomy (PGV). VA Research - Improving Veteran's Care Poster Session. "VA National Research Week," St. Louis, MO, July 6, 1995.
41. Neuberger TJ, Andrus CH, Wittgen CM, Wade TP, Kaminski DL: Prospective comparison of helium versus carbon dioxide pneumoperitoneum. VA Research - Improving Veteran's Care Poster Session, "VA National Research Week," St. Louis, MO, July 6, 1995.
42. Schneider TA, LaRegina ME, Fitzgerald SD, Wittgen CM, Virgo KS, Kaminski DL, Andrus CH: Confirmation of parietal cell distribution by histologic and congo red techniques in a porcine model. VA Research - Improving Veteran's Care Poster Session, "VA National Research Week," St. Louis, MO, July 6, 1995.
43. Neuberger TJ, Wittgen CM, Schneider TA, Andrus CH, Panneton WM, Kaminski DL: Evaluation of alternative PGV techniques in a chronic rat model. VA Research - Improving Veteran's Care Poster Session, "VA National Research Week," St. Louis, MO, July 6, 1995.
44. Andrus CH, Hinder R, Soper N: St. Louis Surgical Fundamental Forum: Laparoscopic Fundoplication (Specific Lecture: The St. Louis Experience to 1995), November 7, 1995.
45. Andrus CH: The Human GI System and Nutrition. Practical Anatomy and Surgical Technique Workshop, St. Louis, MO, January 24, 1996.
46. Andrus CH: Physiological Changes During Laparoscopy. M&M (Blue, Vascular, VAH, Colon/Rectal), Saint Louis University Medical Center, Department of Surgery, St. Louis, MO, February 28, 1996.
47. Andrus CH, Miller GA, Sunwoo YC, Nowlin LJ, Millis BM, JA Ellison, Qualls C: The quality assurance evaluation of an abdominal wound evisceration epidemic!? Poster Presentation for the 49th Annual Southwestern Surgical Congress, April 13-16, 1997, Rancho Mirage, CA.
48. El-Ghazzawy AG, Gupta N, Swope TJ, Kulkarni AD, Panneton WM, Robinson SM, Niehoff ML, Kaminski DL, Andrus CH: Evaluation of benzalkonium chloride chemoneurolytic proximal gastric vagotomy. Surg Endosc 11: 196, 1997. (Abstract & Poster Presentation for the Annual Scientific Meeting of the Society of American Gastrointestinal Endoscopic Surgeons, March 21-22, 1997, San Diego, CA.)
49. Andrus CH, Dries DJ, Romito PJ, Virgo KS: Rationing of surgical care is irrational in the VA. Presented before the Council of Surgery Service Chiefs, Annual Meeting of the Association of Veterans Affairs Surgeons, Louisville, KY, May 5, 1997.
50. Andrus CH: AVAS Council of Chiefs of Surgery representative to the NAVADP's "Physicians' Summit with Congress." Washington, D.C., November 4, 1997. Transcript of meeting published, U.S. Medicine 33 (23 & 24): 1, 29-46, 48, 51, 28; December, 1997.
51. Andrus CH: AVAS Council of Chief's Surgery representative to the NAVADP's "Physicians' Summit." Presented before the Council of Surgery Service Chiefs, Annual Meeting of the Association of Veterans Affairs Surgeons, Baltimore, Maryland, April, 1998.
52. Andrus CH: GI Bleeding. Multidisciplinary Critical Care Board Review Course. Society of Critical Care Medicine. Chicago, Illinois, August 13, 1998.



53. Andrus CH: GI Bleeding. Surgical Grand Rounds, Loyola University, Chicago, Maywood, IL, September 12, 1998.
54. Andrus CH: Minimally Invasive Surgery, Philippine Medical Association in Chicago, Westin Hotel O'Hare, Rosemont, IL, February 6, 1999.
55. Andrus CH, Johnson K, Pierce E, Romito PJ, Hartel P, Berrios-Guccione S, Best W: Finance modeling in the delivery of medical care in tertiary care hospitals in the Department of Veterans Affairs. Presented at the 23rd Annual Meeting Association of VA Surgeons, May 2, 1999. Accepted July 15, 1999 for publication, J Sur Res.
56. Andrus CH: Presentation of a summary of the "Edward Hines, Jr. Veterans Affairs Hospital Surgical and Anesthesia Services FY-99 Annual Report." to Congressional and Senatorial Staffers investigating the VISN 12 Delivery System Options Study (<http://www.va.gov/cno/>), November 23, 1999.
57. Andrus CH: Gastric Dyspepsia: From Beaumont to H. pylori. Loyola University Surgery Grand Rounds. November 11, 2000.
58. Andrus CH: Discussion with U.S. Congressman Henry Hyde, R-6th, and Congressional representatives of the Illinois Senators and northern Illinois Congressmen regarding the VISN 12 Options Study and CARES at the invitation of the Veterans for Unification. The Veterans for Unification Meeting, Broadview Public Library, Broadview, IL, August 30, 2000. This discussion resulted in two published articles:
  1. Wright C: VA hospitals studied again. (Westchester, IL: Westchester Herald, Pioneer Newspapers, Inc., Wednesday, September 6, 2000), vol 15, 24, pages 1, 3, 9.
  2. Wright C: VA hospitals studied again. (Hinsdale Edition: The Doings Newspapers, Pioneer Newspapers, Inc., Thursday, October 19, 2000), vol CVI, no. 3, page 35.
59. Andrus CH, Khuri SF, Daley J: Debate regarding the confidentiality and protection of quality assurance information of the VHA's NSQIP and CICSP. Annual Council of Chiefs meeting, Association of VA Surgeons, American College of Surgeons, October 22, 2000, Chicago, IL.
60. Zapotocky T, Heintz-Miller K, Brayshaw M, Foley S, Lau MT, Byrne R, Andrus CH: A comparison of foley catheters as feeding tubes versus standard gastrostomy tubes. Poster N0044, ASPEN, 25<sup>th</sup> Clinical Congress, Chicago, IL, January 21-24, 2001.
61. Foley, S, Clemmer M, Martling, W, Williams D, Heintz-Miller, K, Lau, MT, Byrne, R, Andrus CH, Reinhardt G: Hypoalbuminemia and mortality in a hospitalized veteran population: Comparison over 20 years. Poster N0014, ASPEN, 25<sup>th</sup> Clinical Congress, Chicago, IL, January 21-24, 2001.
62. Andrus CH: Laparoscopic staging of pancreatic cancer. Surgery Grand Rounds, St. John's Mercy Medical Center, St. Louis, MO, April 19, 2001.
63. Andrus CH: An invited presentation of discussion of CARES at the Council of Chiefs meeting, Association of VA Surgeons, May 6, 2001 in the presence of the Chiefs of Surgery, VHA; the representative of VAHQ Surgery Office, Gerald McDonald, M.D.; and VHA Under Secretary for Health, Thomas Garthwaite, M.D.

64. Andrus CH, Kleinman BS, Mozdierz G, Sinacore JM, Garthwaite TA: Mortality outcomes and attending surgeon presence at the time of operation. Paper podium presentation on May 7, 2003 before the 23<sup>rd</sup> Annual Meeting of the Association for Surgical Education, Vancouver, B.C., Canada, May 6-8, 2003.  
<http://www.surgicaleducation.com/pdf/mortoutcomesattending.pdf> Reviewed by the Association for Surgical Education for final submission and now pending submission to the *American Journal of Surgery*.
65. Andrus CH: Letter to the editor regarding Surgical Quality Measures; re: "The Measure of a Good Surgeon" (GSN, June 2003, page 1). *Gen Surg News* 30 (8): 4, Aug 2003.
66. Andrus CH, Andrus CH: Ethical issues in "Medicine" that Touched our Family. Registered in the Copyright Office of the U.S. Library of Congress, USA, November 10, 2003, ©TXu1-145-557. [Was submitted and has been included in the unpublished BioEthics collection of the Joseph and Rose Kennedy Institute of Ethics, Georgetown University, National Reference Center for Bioethics Literature supported by the U.S. National Library of Medicine. Added to the library's "ETHX on the Web" at <http://bioethics.georgetown.edu> in August, 2004.]
67. Andrus CH: Correspondence from the U.S. Office of Special Counsel in *Andrus v. VA* and Allegations of Obstruction of Justice. Registered in the Copyright Office of the U.S. Library of Congress, March 16, 2004, ©TXu1-165-703. A compilation of documents related to U.S. Court of Appeals for the Federal Circuit Case 03-3162 *Andrus v. VA*.
68. Andrus CH: To Care for Him Who Shall Have Borne the Battle, And for his Widow, and his Orphan—*A. Lincoln*. Registered in the Copyright Office of the U.S. Library of Congress, USA, April 5, 2004, ©TXu1-173-542, (Revised with cover letter, table of contents, and correspondence with the Office of the Counsel to the President: August 24, 2004, ©TXu1-196-220). A compilation of documents related to U.S. Court of Appeals for the Federal Circuit Case 03-3162 *Andrus v. VA*, VA OIG Inspector General Reports regarding VHA Part-Time Physician Time and Attendance and alleged inappropriate transfers of VA patients, and correspondence with the Office of the Counsel to the President. [Was submitted and has been included in the unpublished BioEthics collection of the Joseph and Rose Kennedy Institute of Ethics, Georgetown University, National Reference Center for Bioethics Literature supported by the U.S. National Library of Medicine. Notified on Sept. 13, 2004 that the title and table of contents of this manuscript are to be added to the library's "ETHX on the Web" at <http://bioethics.georgetown.edu> in September/October, 2004]
69. Andrus CH: "*Primum Non Nocere*" and Practicing Ethics in Medicine in this Era of "The Bottom Line." Written and submitted on February 12, 2004 to the *American Journal of Surgery* after receiving a letter of January 22, 2004 of encouragement from the Editor-in-Chief, Hiram C. Polk, M.D., F.A.C.S. Rejected by the Editorial Board of the *American Journal of Surgery* in a letter from Dr. Polk dated April 8, 2004 but posted May 5, 2004 with his recommendation: "...I believe there is a wonderful food for thought and direction as you modify this paper for submission elsewhere." The manuscript was revised and submitted in June, 2004 to the *JAMA*. While Dr. DeAngelis, Editor-in-Chief of *JAMA*, stated that she agreed with the intent and concept, it was felt that *JAMA* could not publish this work. On August 4, 2004, the manuscript was submitted to George D. Lundberg, M.D., Editor, *Medscape General Medicine*, [glundberg@webmd.net](mailto:glundberg@webmd.net), *Web MD* but later was rejected. Copyright protection obtained September 16, 2004, ©TXu1-203-831. Was rejected for publication by the *Kennedy Institute of Ethics Journal*, John Hopkins University Press, November 5, 2004. Was reviewed for consideration for publication but later declined by the *The National Catholic Bioethics Quarterly*. ©TXu1-203-831, September 16, 2004.

70. Andrus CH: *Patient Rights, ERISA, and a boy named Charlie*. Submitted as a Letter-to-the-Editor of the *New England Journal of Medicine*, manuscript #04-2189—but not accepted for publication on July 9, 2004. On August 4, 2004, the manuscript was submitted to George D. Lundberg, M.D., Editor, *Medscape General Medicine*, [glundberg@webmd.net](mailto:glundberg@webmd.net), Web MD. Submitted for to the Copyright Office of the U.S. Library of Congress, October 6, 2004, within the booklet and CD-ROM: *Rationing of Medical Care and the Election of 2004*.
71. Andrus CH: *Rationing of Medical Care and the Election of 2004*. Registered with the Copyright Office of the U.S. Library of Congress, ©TXu1-192-071, October 7, 2004.
72. San Joaquin General Hospital: ERCP during Laparoscopic Cholecystectomy. Submitted by Charles Andrus, M.D. for registration of a San Joaquin General Hospital IRB approved study to the Copyright Office of the U.S. Library of Congress, ©TXu1-262-217, June 27, 2005.
73. Andrus CH: Correspondence regarding the manuscript: *Mortality Outcomes and Attending Surgeon Presence at the Time of Operation*. Registered with the Copyright Office of the U.S. Library of Congress, ©TXu1-262-126, August 29, 2005.
74. Andrus CH: Addendum to: Correspondence regarding the manuscript: *Mortality Outcomes and Attending Surgeon Presence at the Time of Operation*. Registered with the Copyright Office of the U.S. Library of Congress, ©TXu1-274-328, December 2, 2005.
75. Andrus CH: Correspondence regarding aberrancies in attending surgeon supervision of resident surgeons in the VA. Submitted March 13, 2006 for registration to the Copyright Office of the U.S. Library of Congress.
76. Andrus CH: Correspondence regarding aberrancies in attending surgeon supervision of resident surgeons in the VA. Registered with the Copyright Office of the U.S. Library of Congress, ©TXu1-288-808, March 15, 2006.)
77. Andrus PC, Andrus CH: Sonograb. I2P International Competition. Stockholm, Sweden, Nov 16-17, 2012. (Andrus PC: Podium and poster presentation)
78. Andrus CH, Andrus CH, Andrus PB: The ketogenic diet as an energy treatment of complex I deficiencies. Pediatric Research Days, SSM Cardinal Glennon Children's Hospital, SLUSOM, April 11, 2013. (Andrus CH, Andrus CH, Andrus PB: Poster presentation—Mitochondrial drawing – MF Andrus)
79. Khan AA, Jurgens JM, Hubble AA, Andrus CH: Thrombelastographic assessment in chronic disseminated intravascular coagulation (DIC). Missouri Chapter, American College of Surgeons, 46<sup>th</sup> Annual Professional Meeting, Lodge of the Four Seasons, Lake of the Ozarks, Missouri, May 31, 2013. (Khan AA: Podium presentation)
80. Zahra A, Witte AJ, Krampert RM, Andrus CH: Coagulation management during an operation on a uremic patient. Missouri Chapter, American College of Surgeons, 46<sup>th</sup> Annual Professional Meeting, Lodge of the Four Seasons, Lake of the Ozarks, Missouri, June 1, 2013. (Zahra A: Poster presentation)
81. Jasra B, Naunheim KS, Ely E, Andrus CH: Thymoma secreting ectopic parathyroid hormone concomitantly with tertiary hyperparathyroidism. Missouri Chapter, American College of Surgeons, 46<sup>th</sup> Annual Professional Meeting, Lodge of the Four Seasons, Lake of the Ozarks, Missouri, June 1, 2013. (Jasra B: Poster presentation)

82. Nguyen KP, Andrus MF, Naunhiem KS, Andrus CH: Laparoscopic repair of a parahiatal hernia. Missouri Chapter, American College of Surgeons, 46<sup>th</sup> Annual Professional Meeting, Lodge of the Four Seasons, Lake of the Ozarks, Missouri, June 1, 2013. (Andrus CH: Poster presentation)
83. Sun Y, Williams MS, Peterson BG, Andrus CH: Acute and chronic central abdominal venous thrombosis three decades after necrotizing enterocolitis. Missouri Chapter, American College of Surgeons, 47<sup>th</sup> Annual Professional Meeting, Lodge of the Four Seasons, Lake of the Ozarks, Missouri, May 30, 2014. (Sun Y discussant: Poster presentation –First Prize)
84. Gorantla K, Andrus CH, Andrus PC, Andrus CH: Crush protection due to pediatric chest wall malleability? Missouri Chapter, American College of Surgeons, 47<sup>th</sup> Annual Professional Meeting, Lodge of the Four Seasons, Lake of the Ozarks, Missouri, May 30, 2014. (Gorantla A discussant: Poster presentation-Third Prize)
85. Sen R, Sun Y, Andrus MF, Leuhr EA, Andrus CH: Transappendiceal ileoscopy during operative reduction of an ileocolic intussusception. Missouri Chapter, American College of Surgeons, 47<sup>th</sup> Annual Professional Meeting, Lodge of the Four Seasons, Lake of the Ozarks, Missouri, May 30, 2014. (Sen R discussant: Poster presentation)
86. Farrell KA, Salter EE, Andrus CH: The 150 Year promise that irrevocably impacts surgical education to this day. Missouri Chapter, American College of Surgeons, 48<sup>th</sup> Annual Professional Meeting, Lodge of the Four Seasons, Lake of the Ozarks, Missouri, May 31, 2015. (Farrell KA discussant: Podium presentation –Second Prize)
87. Patel S, Sun A, Andrus CH: Is the Cold Appendix acceptable in this era of advanced imaging? Missouri Chapter, American College of Surgeons, 49<sup>th</sup> Annual Professional Meeting, Lodge of the Four Seasons, Lake of the Ozarks, Missouri, June 5, 2016. (Patel S discussant: Podium presentation)
88. Carlson EAJ, Sun Y, Andrus CH: Resolution of a decade of chronic abdominal pain after a laparoscopic incisional hernia repair. Missouri Chapter, American College of Surgeons, 49<sup>th</sup> Annual Professional Meeting, Lodge of the Four Seasons, Lake of the Ozarks, Missouri, June 3, 2016. (Sun Y discussant: Podium presentation)
89. Lobb Jennifer, MD, Diggs L, MD, Andrus CH: Surgical Management of AIDS/HIV Related Gastrointestinal Disease in the Modern Era: A Case Report. Missouri Chapter, American College of Surgeons, 50<sup>th</sup> Annual Professional Meeting, Campden on the Lake, Lake of the Ozarks, Missouri, May 20, 2017. (Lobb J discussant: Podium presentation)
90. LaPlante J, Glasgow S, Andrus C: Terminal ileal adenocarcinoma and synchronous renal cell CA: A Case Report. Missouri Chapter, American College of Surgeons, 50<sup>th</sup> Annual Professional Meeting, Camden of the Lake, Lake of the Ozarks, Missouri, May 20, 2017. (LaPlante discussant: Podium presentation)
91. Dwyer, Emma, Andrus CH: A forgotten chronic deficiency after a historic operation (Vitamin B12 deficiency 7 years after total gastrectomy). MO-Chapter, American College of Surgeons, 51<sup>st</sup> Annual Professional Meeting, Camden on the Lake, Lake of the Ozarks, Missouri, May 11, 2018. (Dwyer discussant: Podium presentation)
92. Henderson CN, Andrus CH: The evaluation and treatment of dyspepsia. MO-Chapter, American College of Surgeons, 51<sup>st</sup> Annual Professional Meeting, Camden on the Lake, Lake of the Ozarks, Missouri, May 11, 2018. (Andrus discussant: Podium presentation)

93. Andrus CH: Changes in ABS recredentialing (American Board of Surgery Continuous Credentialing process), President, MO-Chapter, American College of Surgeons, 51<sup>st</sup> Annual Professional Meeting, Camden on the Lake, Lake of the Ozarks, Missouri, May 11, 2018. (Andrus discussant: Podium presentation)
94. Andrus CH: Presidential Address: The ACS Pledge – Relevance in the Practice of Surgery in the 21<sup>st</sup> Century. President, MO-Chapter, American College of Surgeons, 51<sup>st</sup> Annual Professional Meeting, Camden on the Lake, Lake of the Ozarks, Missouri, May 11, 2018. (Andrus discussant: Podium presentation)
95. Andrus CH: *Physician Vesting in One's Patients – The Core Competencies of Practice-Based Learning and Systems Based Practice*, SLU Department of Surgery, Grand Rounds, 7/25/2018.
96. Khouri AJ, Hou P, Andrus CH: Ischemic colitis in radiographic colonic lipohyperplasia: Getting it right for the wrong reason. MO-Chapter, American College of Surgeons, 52<sup>nd</sup> Annual Professional Meeting, Camden on the Lake, Lake of the Ozarks, Missouri, May 4, 2019.
97. Andrus CH: “The ACGME Forsaken” Competencies: System-based Practice & Practice-based Learning. SLU Department of Surgery, Grand Rounds, 7/10/2019.
98. Andrus CH: Treatment of inguinal hernia in the 21<sup>st</sup> century. SLU Department of Surgery, Grand Rounds, 10/30/2019.
99. Andrus CH: Time: The crucial *Independent Variable* of the COVID-19 pandemic. U.S. Copyright Office, TXu002199029, 6/8/2020.
100. Andrus CH: The Mayo Clinic “Safety Update”<sup>1</sup> should be Classified as a *Completed* Phase I Trial of COVID-19 Convalescent Plasma. U.S. Copyright Office, TXu002214049, July 22, 2020.
101. Andrus CH: 1 Dear Mr President PLEASE COVID-19 Convalescent Plasma NOW 11-17-2020. U.S. Copyright Office, TXu002232947, 11-18-2020.
102. Andrus CH: Letter of December 13, 2020, to the Editors of the NEJM regarding: Simonovich *et al*: *A Randomized Trial of Convalescent Plasma in Covid-19 Severe Pneumonia*. NEJM.org, DIO: 10.1056/NEJMoa2031304, November 24, 2020, 1-11. (Republished by N Engl J Med, February 18, 2021; 384 (7): 619-629). <https://www.nejm.org/doi/pdf/10.1056/NEJMoa2031304?articleTools=true>
104. Andrus CH: E-mail communications with the office of the VHA Under Secretary of Health, Richard A. Stone, M.D. regarding the VA's use of the WRONG Eligibility Criteria for the administration of Remdesivir, VELKURY, NDA 214787, December 20, 2020.
105. Andrus CH: This is a cover letter (e-mail) regarding my letter to the Editors of *The New England Journal of Medicine* regarding: Simonovich VA, Burgos Pratz LD, Sciboona P, et. al.: *A Randomized Trial of Convalescent Plasma in Covid-19 severe pneumonia*, November 24, 2020. (**email attachment item: “41 Letter to editor 12\_13-2020 Not yet sent 12-20-2020.docx”**). Sent December 24, 2020 to the Editors of *The New England Journal of Medicine*.
106. Andrus CH: A letter of January 27, 2021, to Dr. Deborah Birx, M.D., former Chair of the Presidential COVID-19 White House Commission after her interview by Margaret

Brennan on Face the Nation of January 24, 2021: <https://www.cbsnews.com/news/full-transcript-dr-deborah-birx-on-face-the-nation-january-24-2021>.

Continuing Medical Educational (starting July 1, 2020 to present):

7/1/2020 – 6/30/2021: 21 Category 1 credits: Surgical Morbidity and Mortality Conference, VA St. Louis Health Care System – VIM04 FY21, Washington University in St. Louis School of Medicine, St. Louis, MO

7/1/2020 – 6/30/2021: 13 Category 1 credits: General Surgery Grand Rounds, Department of Surgery, Saint Louis University School of Medicine

7/1/2020 – 6/30/2021: 27 Category 1 credits: General Surgery Grand Rounds, Department of Surgery, Saint Louis University School of Medicine

Other Medical Educational Conferences. (starting July 1, 2020 to present)

7/27/2020	VA Core Values Training (I CARE Recommitment), VA TMS
7/27/2020	VHIE Overview Course, VA TMS
7/28/2020	Whistleblower Rights and Protections, VA TMS
7/28/2020	Ensuring Correct Surgery & Invasive Procedures and VHA Directive, VA TMS
8/17/2020	2015 HeartCode BLS, VA TMS
8/18/2020	Telehealth Emergency Plans Memorandum Self-Certification Course, VA TMS
8/18/2020	Telehealth to Home Using VA Video Connect Provider Training, VA TMS
8/19/2020	The EEO, D&I, No FEAR, and Whistleblower Rights and Protection Policy Statement, VA TMS
8/19/2020	Virtual Care Manager Training, VA TMS
8/19/2020	Managing Official Time in VA-TAS, VA TMS
9/14/2020	2015 HeartCode ACLS, VA TMS
9/21/2020	2015 HeartCode ACLS, VA TMS, VA TMS
12/24/2020	VA Caregiver Support Program Expansion Overview 101, VA TMS
4/26/2021	STL Basic Radiation Safety for Fluoroscopy, VA TMS
4/26/2021	STL Pain Management, VA TMS
4/26/2021	STL Preventing Surgical Site Infections: Best Practices, Better Outcomes, VA TMS
5/13/2021	VA Privacy and Information Security Awareness and Rules of Behavior, VA TMS
5/24/2021	Skills Training for Evaluation and Management of Suicide, VA TMS

5/25/2021	Javelin Coaching Session with Steve Sons
6/1/2020	Javelin Coaching Session with Steve Sons
6/17/2020	Javelin Coaching Session with Fred Fishback –4939 125 <sup>th</sup> Avenue, South, Wellington, FL 33449
6/24/2020	Javelin Coaching Session with Fred Fishback
8/9/2021	VA Core Values Training (I CARE Recommitment), VA TMS
7/8/2021	Javelin Coaching Session with Fred Fishback
8/9/2021	Prevention of Workplace Harassment/NoFEAR, VA TMS
8/9/2021	Privacy and HIPPA Training, VA TMS
8/9/2021	General Integrity and Compliance Awareness Training Test Out Option, VA TMS
8/10/2021	Government Ethics –The Essentials, VA TMS





Revised 8/12/2019

## CURRICULUM VITAE

Charles H. Andrus, M.D., F.A.C.S.

### A. Personal Information:

Home address	150 Emerald Green Court Creve Coeur, MO 63141 (314) 455-9482
Marital status	Married Pamela Bergkamp Andrus 7/27/87
Children	Charles Harold Andrus - 1/25/87 Patrick Christopher Andrus - 3/18/89 Thomas Mark Andrus - 7/9/92 Michael Francis Andrus - 5/3/96 Timothy Stephen Andrus - 8/3/97
Birth Date	March 28, 1953
Citizenship	U.S.
Social Security Number	XXX-XX-XXXX
Medicare	2018 XXX-XXX-XXXX

### B. Education:

#### *Undergraduate degree and major*

University of San Francisco, 1971-1975  
San Francisco, CA 94117  
BS in Chemistry (Amer. Chemical Soc. approved degree)  
Summa cum Laude

Cal State University at San Francisco, 1973 (summers)  
1600 Holloway Ave.  
San Francisco, CA 94132  
General Zoology and General Botany

#### *Graduate degree and major*

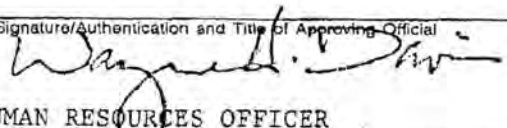
Saint Louis University School of Medicine, 1975-79  
1402 South Grand Blvd.  
St. Louis, MO 63104  
M.D. conferred May 12, 1979



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Standard Form 50  
Rev. 7/91  
U.S. Office of Personnel Management  
FPM Supp. 296-33, Subch. 4

## NOTIFICATION OF PERSONNEL ACTION

1. Name (Last, First, Middle) ANDRUS, CHARLES H.				2. Social Security Number 563-94-2723		3. Date of Birth 03-28-53		4. Effective Date 01-19-2002			
<b>FIRST ACTION</b>				<b>SECOND ACTION</b>							
5-A. Code 317		5-B. Nature of Action RESIGNATION		6-A. Code		6-B. Nature of Action					
5-C. Code RUM		5-D. Legal Authority REG. 715.202 OTHER		6-C. Code		6-D. Legal Authority					
5-E. Code		5-F. Legal Authority		6-E. Code		6-F. Legal Authority					
7. FROM: Position Title and Number PHYSICIAN 000000				15. TO: Position Title and Number							
8. Pay Plan AD		9. Occ. Code 0602		10. Grade/Level CHIEF		11. Step/Rate 10		12. Total Salary \$107,357		13. Pay Basis PA	
16. Pay Plan		17. Occ. Code		18. Grade/Level		19. Step/Rate		20. Total Salary/Award		21. Pay Basis	
12A. Basic Pay \$107,357		12B. Locality Adj. \$0		12C. Adj. Basic Pay \$107,357		12D. Other Pay \$0		20A. Basic Pay		20B. Locality Adj.	
20C. Adj. Basic Pay		20D. Other Pay									
14. Name and Location of Position's Organization VA MEDICAL CENTER PATIENT CARE SVCS SURGICAL SERVICE HINES IL				22. Name and Location of Position's Organization							
<b>EMPLOYEE DATA</b>											
23. Veterans Preference 1 - None 2 - 5-Point 3 - 10-Point/Disability 4 - 10-Point/Compensable 5 - 10-Point/Other 6 - 10-Point/Compensable/30%				24. Tenure 1 - None 2 - Permanent 3 - Conditional 4 - Indefinite				25. Agency Use		26. Veterans Preference for RIF YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>	
27. FEGLI CO BASIC LIFE ONLY				28. Annuitant Indicator 9 NOT APPLICABLE				29. Pay Rate Determinant 0			
30. Retirement Plan K FERS & FICA				31. Service Comp. Date (Leave) 04-07-83				32. Work Schedule P PART-TIME		33. Part-Time Hours Per Biweekly Pay Period 70	
<b>POSITION DATA</b>				35. FLSA Category E - Exempt N - Nonexempt				36. Appropriation Code 8202.2280		37. Bargaining Unit Status 7777	
34. Position Occupied 2 - Competitive Service 3 - SES General 4 - SES Career Reserved				38. Duty Station Code 17-397-031				39. Duty Station (City - County - State or Overseas Location) HINES IL			
40. AGENCY DATA		41.		42.		43.		44.			
45. Remarks  REASON FOR RESIGNATION: MY RESIGNATION AS A PHYSICIAN AND SURGEON OF THE DEPARTMENT OF VETERANS AFFAIRS CAN BE CONSTRUED AS A CONSTRUCTIVE DISCHARGE. AS SUCH, THE VA OIF FAILED TO INVESTIGATE OR ADDRESS ALLEGATIONS OF DENIAL AND DELAY OF ELIGIBLE MEDICAL CARE TO VETERANS; DOCUMENTATION WAS DESTROYED BY A PUBLIC ACCOUNTING FIRM BY ORDER OF A VA OFFICIAL IN THE PREPARATION OF AN OFFICIAL VA STUDY, AND I PERSONALLY WAS THE SUBJECT OF MULTIPLE PROHIBITIVE PERSONNEL PRACTICES ALLEGED TO HAVE ORIGINATED AT THE ORDERS OF THE VISA 12 DIRECTOR, JOAN E. CUMMINGS, M.D. (VISA DIRECTED TERMINATION OF MY EMPLOYMENT AS DISCUSSED WITH THE HINES VAH DIRECTOR DENARDO AND DOCUMENTED IN DEPOSITIONS BY ROBYN HANNA IN JULY, 1999 OF THE VA OIG). TO FULLY UNDERSTAND THE CONSTRUCTIVE DISCHARGE, ONE SHOULD REVIEW U.S. OSC #MA-00-1107 AND DI-00-1147; VA OIG 9HL-015, 2000HL-0347, AND 2001-01512-HL-0544; AND DVA/ORM 200K-1886. WITHOUT THIS CONSTRUCTIVE DISCHARGE, I HAD PLANNED TO CONTINUE IN MY CURRENT POSITION UNTIL RETIREMENT (ANOTHER 19 YEARS HOPEFULLY) AS THE CHIEF, SURGERY SERVICE, EDWARD HINES, JR., VAH CHICAGO.											
46. Employing Department or Agency DEPARTMENT OF VETERANS AFFAIRS						50. Signature/Authentication and Title of Approving Official  HUMAN RESOURCES OFFICER					
47. Agency Code VA TA		48. Personnel Office ID 1255		49. Approval Date 01-19-2002							

TURN OVER FOR IMPORTANT INFORMATION  
5-Part 50-156

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Editions Prior to 7/91 Are Not Usable After 6/30/93  
NSN 7540-01-333-6236

## NOTICE OF EMPLOYMENT

and a copy of the official notice of a position  
to make employment, pay, and benefits.

2002 January 15 - 2002 January 15

1. The position is located in the personnel section, and the position is located in the personnel section.

2. The position is located in the personnel section, and the position is located in the personnel section.

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## OTHER INFORMATION

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It is your responsibility to read all the information in the form of this notice and call your personnel specialist immediately.

3 of 26

Standard Form 50-8

Rev. 7/91

U.S. Office of Personnel Management

FPM Supp. 296-33, Subch. 4

## NOTIFICATION OF PERSONNEL ACTION

578 578

1. Name (Last, First, Middle) <b>ANDRUS, CHARLES H</b>		2. Social Security Number <b>563-94-2723</b>	3. Date of Birth <b>03-28-53</b>	4. Effective Date <b>01-19-2002</b>
5-A. Code <b>317</b>		5-B. Nature of Action <b>RESIGNATION</b>		
5-C. Code <b>RUM</b>		5-D. Legal Authority <b>REG. 715.202 OTHER</b>		
5-E. Code		5-F. Legal Authority		

7. FROM: Position Title and Number <b>PHYSICIAN</b>  <b>000000</b>					15. TO: Position Title and Number							
8. Pay Plan <b>AD</b>	9. Occ. Code <b>0602</b>	10. Grade/Level <b>CHIEF</b>	11. Step/Rate <b>10</b>	12. Total Salary <b>\$107,357</b>	13. Pay Basis <b>PA</b>	16. Pay Plan	17. Occ. Code	18. Grade/Level	19. Step/Rate	20. Total Salary/Award	21. Pay Basis	
12A. Basic Pay <b>\$107,357</b>		12B. Locality Adj. <b>\$0</b>		12C. Adj. Basic Pay <b>\$107,357</b>		12D. Other Pay <b>\$0</b>		20A. Basic Pay		20B. Locality Adj.	20C. Adj. Basic Pay	20D. Other Pay
14. Name and Location of Position's Organization  <b>VA MEDICAL CENTER</b> <b>PATIENT CARE SVCS SURGICAL SERVICE</b> <b>HINES IL</b>						22. Name and Location of Position's Organization						

23. Veterans Preference <b>1</b> 1 - None 2 - 5-Point 3 - 10-Point/Disability 4 - 10-Point/Compensable 5 - 10-Point/Other 6 - 10-Point/Compensable/30%				24. Tenure <b>1</b> 0 - None 1 - Permanent 2 - Conditional 3 - Indefinite		25. Agency Use		26. Veterans Preference for RIF <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO	
27. FEGLI <b>CO BASIC LIFE ONLY</b>				28. Annuitant Indicator <b>9 NOT APPLICABLE</b>		29. Pay Rate Determinant <b>0</b>			
30. Retirement Plan <b>K FERS &amp; FICA</b>				31. Service Comp. Date (Leave) <b>04-07-83</b>		32. Work Schedule <b>P PART-TIME</b>		33. Part-Time Hours Per Biweekly Pay Period <b>70</b>	
34. Position Occupied <b>2</b> 1 - Competitive Service 2 - Excepted Service 3 - SES General 4 - SES Career Reserved				35. FLSA Category <b>E</b> E - Exempt N - Nonexempt		36. Appropriation Code <b>8202.2280</b>		37. Bargaining Unit Status <b>7777</b>	
38. Duty Station Code <b>17-3975-031</b>				39. Duty Station (City - County - State or Overseas Location) <b>HINES IL</b>					
40. AGENCY DATA		41.	42.	43.	44.				

## 45. Remarks

ASSIGNMENT: SURGERY

LUMP SUM PAYMENT TO BE MADE FOR ANY UNUSED ANNUAL LEAVE.

## FORWARDING ADDRESS:

\* 4269 BOULDER CREEK CIRCLE  
\* STOCKTON, CALIFORNIA 95219

## FORWARDING ADDRESS:

\*  
\*

REMARKS CONTINUED ON NEXT PAGE

46. Employing Department or Agency <b>DEPARTMENT OF VETERANS AFFAIRS</b>			50. Signature/Authentication and Title of Approving Official  <i>Wayne L. Davis</i> <b>HUMAN RESOURCES OFFICER</b>	
47. Agency Code <b>VA TA</b>	48. Personnel Office ID <b>1255</b>	49. Approval Date <b>01-19-2002</b>		

TURN OVER FOR IMPORTANT INFORMATION

5-Part 50-316

1 - Employee Copy - Keep for Future Reference

Editions Prior to 7/91 Are Not Usable After 6/30/83  
NSN 7540-01-333-8238

## NOTICE TO EMPLOYEE

This is your copy of the official notice of a personnel action. Keep it with your records because it could be used to make employment, pay, and qualifications decisions about you in the future.

### The Action

- Blocks 5-B and 6-B describe the personnel action(s) that occurred.
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### Pay

- When the personnel action is an award or bonus, block 20 shows the amount of that one-time cash payment. When the action is not an award or bonus, block 12 shows your former total annual salary, and block 20 shows your new total annual salary (block 20C plus 20D). The amounts in blocks 12 and 20 do not include any one-time cash payments (such as performance awards and recruitment or relocation bonuses) or payments that may vary from one pay period to the next (such as overtime pay), or other forms of premium pay.
- Block 20A is the scheduled amount for your grade and step, including any special salary rate you receive. It does not include any locality-based pay. This rate of pay serves as the basis for determining your rate of pay upon promotion, change to a lower grade, or reassignment, and is used for pay retention purposes.
- Block 20B is the annual dollar amount of your Interim Geographic Adjustment or, beginning in 1994, your locality-based comparability payment.
- Block 20C is your Adjusted Basic Pay, the total of blocks 20A and 20B. It serves as the basis for computing your retirement benefits, life insurance, premium pay, and severance pay.
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### Block 24 – Tenure

- Identifies the nature of your appointment and is used to determine your rights during a reduction in force (RIF). Tenure groups are explained in more detail in subchapter 26 of FPM Supplement 296-33 and RIF is explained in FPM Supplement 351-1; both should be available for review in your personnel office.

### Block 26 – Veterans Preference for RIF

- Indicates whether you have preference for reduction-in-force purposes.

### Block 30 – Retirement Plan

- FICA —Social Security System
- CS —Civil Service Retirement System
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- FS —Foreign Service Retirement and Disability System
- FERS —Federal Employees' Retirement System
- FERS-Reserve Tech —Federal Employees' Retirement System for National Guard Reserve Technicians
- FERS-ATC —Federal Employees' Retirement System for air Traffic Controllers
- FERS-Spec —Federal Employees' Retirement System for law enforcement and firefighter personnel
- FSPS —Foreign Service Pension System

### Block 31 – Service Computation Date (Leave)

- Shows when your Federal service began unless you have prior creditable service. If so, this date is constructed to include your total years, months and days of prior creditable civilian and military service.
- Full-time employees with fewer than 3 years of service earn 4 hours of annual leave each pay period; those with 3 or more years but less than 15 years earn 6 hours each pay period; and those with 15 or more years earn 8 hours each pay period.
- Your earnings and leave statement or your time and attendance card will show the rate at which you earn leave and your current unused leave balance.

### Block 32 – Work Schedule

- Your work schedule is established by your supervisor.
- A full-time employee works on a prearranged scheduled tour of duty that is usually 40 hours per week. A part-time employee has a prearranged scheduled tour of duty that is usually between 16 and 32 hours per week. An intermittent employee has no prearranged scheduled tour of duty and works when needed.
- Full-time and part-time employees whose appointments are for 90 days or more are usually eligible to earn annual leave; intermittent employees are not.
- Seasonal employees work on an annually recurring basis for periods of less than 12 months each year; they may have a full-time, a part-time, or an intermittent schedule during their work season.
- On-call employees work during periods of heavy workload and are in pay status for at least 6 months of each year; they may have either a full-time or a part-time schedule when they are in pay status.

### Block 33 – Part-time Hours Per Biweekly Pay Period

- Indicates the number of hours a part-time employee is scheduled to work during a two-week pay period.

### Block 34 – Position Occupied

- Identifies the employment system under which you are serving — the Competitive Service, the Excepted Service, or the Senior Executive Service (SES).
- The employment system determines your eligibility to move to other jobs in the Federal service, your rights in disciplinary and adverse actions, and your eligibility for reemployment if you leave Federal service.

### Block 35 – FLSA Category

- Exempt employees are not covered by the minimum wage and overtime law (the Fair Labor Standards Act); nonexempt employees are covered.

### Block 37 – Bargaining Unit Status

- Identifies a bargaining unit to which you belong; whether or not you are actually a member of a labor organization. Code "7777" indicates you are eligible but not in a bargaining unit; code "8888" indicates you are ineligible for inclusion in a bargaining unit.

### Blocks 38 and 39 – Duty Station

- Identifies the city, county, and state or the overseas location, where you actually work.

## OTHER INFORMATION

- If your appointment entitles you to elect health benefits or life insurance, and you have not been provided materials explaining the programs available and the enrollment forms, contact your personnel specialist.
- Your personnel specialist will also tell you if your position is covered by an agreement between an employee organization (union) and your agency. If you are eligible to and elect to join an employee organization, you can elect to have your dues withheld from your salary.
- If you have questions or need more information about your rights and benefits, ask your supervisor or your personnel office.
- Definitions for any coded data in Blocks 1-24, 27-39 and 45-50 may be found in Federal Personnel Manual Supplement 292-1.

It is your responsibility to read all the information on the front of this notice and tell your personnel office immediately if there is an error in it.



Standard Form 50-B

Rev. 7/91

U.S. Office of Personnel Management

FPM Supp. 296-33, Subch. 4

## NOTIFICATION OF PERSONNEL ACTION

578 578

1. Name (Last, First, Middle) <b>ANDRUS, CHARLES H</b>		2. Social Security Number <b>563-94-2723</b>	3. Date of Birth <b>03-28-53</b>	4. Effective Date <b>01-19-2002</b>
5-A. Code <b>317</b>		5-B. Nature of Action <b>RESIGNATION</b>		
5-C. Code <b>RUM</b>		5-D. Legal Authority <b>REG. 715.202 OTHER</b>		
5-E. Code		5-F. Legal Authority		

7. FROM: Position Title and Number <b>PHYSICIAN</b>  <b>000000</b>						15. TO: Position Title and Number					
8. Pay Plan <b>AG</b>	9. Occ. Code <b>0602</b>	10. Grade/Level <b>CHIEF</b>	11. Step/Rate <b>10</b>	12. Total Salary <b>\$107,357</b>	13. Pay Basis <b>PA</b>	16. Pay Plan	17. Occ. Code	18. Grade/Level	19. Step/Rate	20. Total Salary/Award	21. Pay Basis
12A. Basic Pay <b>\$107,357</b>	12B. Locality Adj. <b>\$0</b>	12C. Adj. Basic Pay <b>\$107,357</b>	12D. Other Pay <b>\$0</b>	20A. Basic Pay	20B. Locality Adj.	20C. Adj. Basic Pay	20D. Other Pay				
14. Name and Location of Position's Organization  <b>VA MEDICAL CENTER</b> <b>PATIENT CARE SVCS SURGICAL SERVICE</b> <b>HINES IL</b>						22. Name and Location of Position's Organization					

23. Veterans Preference <b>1</b> 1 - None 2 - 5-Point 3 - 10-Point/Disability 4 - 10-Point/Compensable 5 - 10-Point/Other 6 - 10-Point/Compensable/30%				24. Tenure <b>1</b> 0 - None 1 - Permanent 2 - Conditional 3 - Indefinite		25. Agency Use		26. Veterans Preference for RIF <b>YES</b> <input checked="" type="checkbox"/> <b>NO</b>	
27. FEGLI <b>CO BASIC LIFE ONLY</b>				28. Annuitant Indicator <b>9 NOT APPLICABLE</b>		29. Pay Rate Determinant <b>0</b>			
30. Retirement Plan <b>K PERS &amp; FICA</b>		31. Service Comp. Date (Leave) <b>04-07-83</b>		32. Work Schedule <b>P PART-TIME</b>		33. Part-Time Hours Per Biweekly Pay Period <b>70</b>			
34. Position Occupied <b>2</b> 1 - Competitive Service 2 - Excepted Service 3 - SES General 4 - SES Career Reserved				35. FLSA Category <b>E</b> E - Exempt N - Nonexempt		36. Appropriation Code <b>8202-2280</b>		37. Bargaining Unit Status <b>7777</b>	
38. Duty Station Code <b>17-3975-031</b>				39. Duty Station (City - County - State or Overseas Location) <b>HINES IL</b>					
40. AGENCY DATA		41.	42.	43.	44.				

45. Remarks

REMARKS CONTINUED:

HEALTH BENEFITS COVERAGE IS EXTENDED FOR 31 DAYS DURING WHICH YOU ARE ELIGIBLE TO CONVERT TO AN INDIVIDUAL POLICY (NONGROUP CONTRACT).

SF 2819 WAS PROVIDED. LIFE INSURANCE IS EXTENDED FOR 31 DAYS DURING WHICH YOU ARE ELIGIBLE TO CONVERT TO AN INDIVIDUAL POLICY (NONGROUP CONTRACT).

46. Employing Department or Agency <b>DEPARTMENT OF VETERANS AFFAIRS</b>			50. Signature/Authentication and Title of Approving Official  <i>Wayne L. Davis</i> <b>HUMAN RESOURCES OFFICER</b>	
47. Agency Code <b>VA TA</b>	48. Personnel Office ID <b>1255</b>	49. Approval Date <b>01-19-2002</b>		

TURN OVER FOR IMPORTANT INFORMATION

5-Part 50-316

1 - Employee Copy - Keep for Future Reference

Editions Prior to 7/91 Are Not Usable After 6/30/93  
NSN 7540-01-333-6238

## NOTICE TO EMPLOYEE

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### The Action

- Blocks 5-B and 6-B describe the personnel action(s) that occurred.
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- When the personnel action is an award or bonus, block 20 shows the amount of that one-time cash payment. When the action is not an award or bonus, block 12 shows your former total annual salary, and block 20 shows your new total annual salary (block 20C plus 20D). The amounts in blocks 12 and 20 do not include any one-time cash payments (such as performance awards and recruitment or relocation bonuses) or payments that may vary from one pay period to the next (such as overtime pay), or other forms of premium pay.
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- Identifies the nature of your appointment and is used to determine your rights during a reduction in force (RIF). Tenure groups are explained in more detail in subchapter 26 of FPM Supplement 296-33 and RIF is explained in FPM Supplement 351-1; both should be available for review in your personnel office.

### Block 26 – Veterans Preference for RIF

- Indicates whether you have preference for reduction-in-force purposes.

### Block 30 – Retirement Plan

- FICA —Social Security System
- CS —Civil Service Retirement System
- CS-Spec —Civil Service Retirement System for law enforcement and firefighter personnel
- FS —Foreign Service Retirement and Disability System
- FERS —Federal Employees' Retirement System
- FERS-Reserve Tech —Federal Employees' Retirement System for National Guard Reserve Technicians
- FERS-ATC —Federal Employees' Retirement System for Air Traffic Controllers
- FERS-Spec —Federal Employees' Retirement System for law enforcement and firefighter personnel
- FSPS —Foreign Service Pension System

### Block 31 – Service Computation Date (Leave)

- Shows when your Federal service began unless you have prior creditable service. If so, this date is constructed to include your total years, months and days of prior creditable civilian and military service.
- Full-time employees with fewer than 3 years of service earn 4 hours of annual leave each pay period; those with 3 or more years but less than 15 years earn 6 hours each pay period; and those with 15 or more years earn 8 hours each pay period.
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- On-call employees work during periods of heavy workload and are in pay status for at least 6 months of each year; they may have either a full-time or a part-time schedule when they are in pay status.

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- Indicates the number of hours a part-time employee is scheduled to work during a two-week pay period.

### Block 34 – Position Occupied

- Identifies the employment system under which you are serving — the Competitive Service, the Excepted Service, or the Senior Executive Service (SES).
- The employment system determines your eligibility to move to other jobs in the Federal service, your rights in disciplinary and adverse actions, and your eligibility for reemployment if you leave Federal service.

### Block 35 – FLSA Category

- Exempt employees are not covered by the minimum wage and overtime law (the Fair Labor Standards Act); nonexempt employees are covered.

### Block 37 – Bargaining Unit Status

- Identifies a bargaining unit to which you belong, whether or not you are actually a member of a labor organization. Code "7777" indicates you are eligible but not in a bargaining unit; code "8888" indicates you are ineligible for inclusion in a bargaining unit.

### Blocks 38 and 39 – Duty Station

- Identifies the city, county, and state or the overseas location, where you actually work.

## OTHER INFORMATION

- If your appointment entitles you to elect health benefits or life insurance, and you have not been provided materials explaining the programs available and the enrollment forms, contact your personnel specialist.
- Your personnel specialist will also tell you if your position is covered by an agreement between an employee organization (union) and your agency. If you are eligible to and elect to join an employee organization, you can

elect to have your dues withheld from your salary.

- If you have questions or need more information about your rights and benefits, ask your supervisor or your personnel office.
- Definitions for any coded data in Blocks 1-24, 27-39 and 45-50 may be found in Federal Personnel Manual Supplement 292-1.

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Standard Form 50-B  
Rev. 7/91  
U.S. Office of Personnel Management  
FPM Supp. 296-33, Subch. 4

# NOTIFICATION OF PERSONNEL ACTION

578 578

1. Name (Last, First, Middle) ANDERSON, JAMES H		2. Social Security Number 503-94-2723	3. Date of Birth 03-20-53	4. Effective Date 01-27-2002
<b>FIRST ACTION</b>				
5-A. Code 004	5-B. Nature of Action PAY ADJUSTMENT			
5-C. Code VAW	5-D. Legal Authority 35 USC 5515 (a)(1)(A) 5 USC 5305 (a)(1)(A)			
5-E. Code	5-F. Legal Authority			
6-A. Code		6-B. Nature of Action		
6-C. Code		6-D. Legal Authority		
6-E. Code		6-F. Legal Authority		

7. FROM: Position Title and Number PHYSICIAN 000000										15. TO: Position Title and Number PHYSICIAN 000000									
8. Pay Plan AD 0000	9. Occ. Code CHIEF	10. Grade/Level 10	11. Step/Rate 10	12. Total Salary \$107,357	13. Pay Basis PA	16. Pay Plan AD 0000	17. Occ. Code CHIEF	18. Grade/Level 10	19. Step/Rate 10	20. Total Salary/Award \$107,357	21. Pay Basis PA								
12A. Basic Pay \$107,357	12B. Locality Adj. 00	12C. Adj. Basic Pay \$107,357	12D. Other Pay 00	20A. Basic Pay \$107,357	20B. Locality Adj. 00	20C. Adj. Basic Pay \$107,357	20D. Other Pay 00												
14. Name and Location of Position's Organization VA MEDICAL CENTER PATIENT CARE SVCS SURGICAL SERVICE HINES IL						22. Name and Location of Position's Organization VA MEDICAL CENTER PATIENT CARE SVCS SURGICAL SERVICE HINES IL													

## EMPLOYEE DATA

23. Veterans Preference 1 - None 2 - 5-Point 3 - 10-Point/Disability 4 - 10-Point/Compensable 5 - 10-Point/Other 6 - 10-Point/Compensable/30%				24. Tenure 1 - None 2 - Conditional 3 - Permanent 4 - Indefinite		25. Agency Use		26. Veterans Preference for RIF YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>	
27. FEGLI LIFE ONLY				28. Annuitant Indicator NOT APPLICABLE		29. Pay Rate Determinant 0			
30. Retirement Plan R				31. Service Comp. Date (Leave) 09-07-03		32. Work Schedule PART-TIME		33. Part-Time Hours Per Biweekly Pay Period 70	
34. Position Occupied 2 1 - Competitive Service 2 - Excepted Service 3 - SES General 4 - SES Career Reserved				35. FLSA Category E - Exempt N - Nonexempt		36. Appropriation Code 0202-2200		37. Bargaining Unit Status 7777	
38. Duty Station Code 17-0510-001				39. Duty Station (City - County - State or Overseas Location) HINES IL					

40. AGENCY DATA	41.	42.	43.	44.
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45. Remarks ADJUSTMENT NOTE: ADJUSTMENT SPECIAL PAY DISCONTINUED.				
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46. Employing Department or Agency DEPARTMENT OF VETERANS AFFAIRS			50. Signature/Authentication and Title of Approving Official [Signature] HUMAN RESOURCES OFFICER	
47. Agency Code VA	48. Personnel Office ID HPL	49. Approval Date 01-27-2002		



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Standard Form 50-B  
Rev. 7/91  
U.S. Office of Personnel Management  
FPM Supp. 296-33, Subch. 4

# NOTIFICATION OF PERSONNEL ACTION

578 578

1. Name (Last, First, Middle) <b>ANDRUS, CHARLES H</b>		2. Social Security Number <b>563-94-2723</b>	3. Date of Birth <b>03-28-53</b>	4. Effective Date <b>01-03-1999</b>
5-A. Code <b>002</b>		5-B. Nature of Action <b>CORRECTION</b>		
5-C. Code		5-D. Legal Authority		
5-E. Code		5-F. Legal Authority		

7. FROM: Position Title and Number <b>PHYSICIAN</b> <b>000000</b>										15. TO: Position Title and Number <b>PHYSICIAN</b> <b>000000</b>													
8. Pay Plan <b>AD</b>		9. Occ. Code <b>0602</b>		10. Grade/Level <b>CHIEF</b>		11. Step/Rate <b>10</b>		12. Total Salary <b>\$97,201</b>		13. Pay Basis <b>PA</b>		16. Pay Plan <b>AD</b>		17. Occ. Code <b>0602</b>		18. Grade/Level <b>CHIEF</b>		19. Step/Rate <b>10</b>		20. Total Salary/Award <b>\$97,201</b>		21. Pay Basis <b>* PA</b>	
12A. Basic Pay <b>\$97,201</b>		12B. Locality Adj. <b>\$0</b>		12C. Adj. Basic Pay <b>\$97,201</b>		12D. Other Pay <b>\$0</b>		20A. Basic Pay <b>\$97,201</b>		20B. Locality Adj. <b>\$0</b>		20C. Adj. Basic Pay <b>\$97,201</b>		20D. Other Pay <b>\$0</b>									
14. Name and Location of Position's Organization <b>VA MEDICAL CENTER</b> <b>PATIENT CARE SVCS SURGICAL SERVICE</b> <b>HINES IL</b>												22. Name and Location of Position's Organization <b>VA MEDICAL CENTER</b> <b>PATIENT CARE SVCS SURGICAL SERVICE</b> <b>HINES IL</b>											

## EMPLOYEE DATA

23. Veterans Preference <b>1</b> 1 - None 2 - 5-Point 3 - 10-Point/Disability 4 - 10-Point/Compensable 5 - 10-Point/Other 6 - 10-Point/Compensable/30%				24. Tenure <b>1</b> 0 - None 1 - Permanent 2 - Conditional 3 - Indefinite		25. Agency Use		26. Veterans Preference for RIF <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO	
27. FEGLI <b>CO BASIC LIFE ONLY</b>				28. Annuitant Indicator <b>9 NOT APPLICABLE</b>		29. Pay Rate Determinant <b>0</b>			
30. Retirement Plan <b>K FERS &amp; FICA</b>				31. Service Comp. Date (Leave) <b>04-07-83</b>		32. Work Schedule <b>P PART-TIME</b>		33. Part-Time Hours Per Biweekly Pay Period <b>70</b>	
34. Position Occupied <b>2</b> 1 - Competitive Service 2 - Excepted Service 3 - SES General 4 - SES Career Reserved				35. FLSA Category <b>E</b> E - Exempt N - Nonexempt		36. Appropriation Code <b>8202.2280</b>		37. Bargaining Unit Status <b>7777</b>	
38. Duty Station Code <b>17-3975-031</b>				39. Duty Station (City - County - State or Overseas Location) <b>HINES IL</b>					
40. AGENCY DATA		41.		42.		43.		44.	

## 45. Remarks

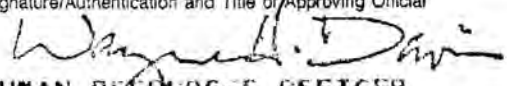
**ASSIGNMENT: SURGERY**

**\*NTE 1820 HR PA**

**\$45 REMARKS REGARDING SPECIAL PAY FROM \$47,000 TO \$50,000**

**CORRECTS ITEM/S/\***

**\*\*+ \$ 50,000 SPECIAL PAY AUTHORIZED UNDER 38 U.S.C. 7431 NTE**  
**\* CO-CO-0000. SPECIAL PAY IS BASE PAY FOR RETIREMENT AND LIFE**  
**INSURANCE PURPOSES, BUT NOT FOR PURPOSES OF ANY OTHER BENEFIT RELATED**  
**TO BASIC PAY. FOR PART-TIME SERVICE, PAYMENT IS PRORATED BASED ON**  
**RATIO TO FULL-TIME SERVICE NTE THREE-FOURTHS.**

48. Employing Department or Agency <b>DEPARTMENT OF VETERANS AFFAIRS</b>			50. Signature/Authentication and Title of Approving Official  <b>HUMAN RESOURCES OFFICER</b>		
47. Agency Code <b>VA TA</b>	48. Personnel Office ID <b>1255</b>	49. Approval Date <b>01-01-1999</b>			

TURN OVER FOR IMPORTANT INFORMATION

5-Part 50-318

1 - Employee Copy - Keep for Future Reference

Editions Prior to 7/91 Are Not Usable After 6/30/  
NSN 7540-01-333-62

## NOTICE TO EMPLOYEE

This is your copy of the official notice of a personnel action. Keep it with your records because it could be used to make employment, pay, and qualifications decisions about you in the future.

### The Action

- Blocks 5-B and 6-B describe the personnel action(s) that occurred.
- Blocks 15-22 show the position and organization to which you are assigned.

### Pay

- When the personnel action is an award or bonus, block 20 shows the amount of that one-time cash payment. When the action is not an award or bonus, block 12 shows your former total annual salary, and block 20 shows your new total annual salary (block 20C plus 20D). The amounts in blocks 12 and 20 do not include any one-time cash payments (such as performance awards and recruitment or relocation bonuses) or payments that may vary from one pay period to the next (such as overtime pay), or other forms of premium pay.
- Block 20A is the scheduled amount for your grade and step, including any special salary rate you receive. It does not include any locality-based pay. This rate of pay serves as the basis for determining your rate of pay upon promotion, change to a lower grade, or reassignment, and is used for pay retention purposes.
- Block 20B is the annual dollar amount of your Interim Geographic Adjustment or, beginning in 1994, your locality-based comparability payment.
- Block 20C is your Adjusted Basic Pay, the total of blocks 20A and 20B. It serves as the basis for computing your retirement benefits, life insurance, premium pay, and severance pay.
- Block 20D is the total dollar amount of any Retention Allowances, Supervisory Differentials, and Staffing Differentials that are listed in the remarks block. These payments are made in the same manner as basic pay, but are not a part of basic pay for any purpose.

### Block 24 – Tenure

- Identifies the nature of your appointment and is used to determine your rights during a reduction in force (RIF). Tenure groups are explained in more detail in subchapter 26 of FPM Supplement 296-33 and RIF is explained in FPM Supplement 351-1; both should be available for review in your personnel office.

### Block 26 – Veterans Preference for RIF

- Indicates whether you have preference for reduction-in-force purposes.

### Block 30 – Retirement Plan

- FICA — Social Security System
- CS — Civil Service Retirement System
- CS-Spec — Civil Service Retirement System for law enforcement and firefighter personnel
- FS — Foreign Service Retirement and Disability System
- FERS — Federal Employees' Retirement System
- FERS-Reserve Tech — Federal Employees' Retirement System for National Guard Reserve Technicians
- FERS-ATC — Federal Employees' Retirement System for Air Traffic Controllers
- FERS-Spec — Federal Employees' Retirement System for law enforcement and firefighter personnel
- FSPS — Foreign Service Pension System

### Block 31 – Service Computation Date (Leave)

- Shows when your Federal service began unless you have prior creditable service. If so, this date is constructed to include your total years, months and days of prior creditable civilian and military service.
- Full-time employees with fewer than 3 years of service earn 4 hours of annual leave each pay period; those with 3 or more years but less than 15 years earn 6 hours each pay period; and those with 15 or more years earn 8 hours each pay period.
- Your earnings and leave statement or your time and attendance card will show the rate at which you earn leave and your current unused leave balance.

### Block 32 – Work Schedule

- Your work schedule is established by your supervisor.
- A full-time employee works on a prearranged scheduled tour of duty that is usually 40 hours per week. A part-time employee has a prearranged scheduled tour of duty that is usually between 16 and 32 hours per week. An intermittent employee has no prearranged scheduled tour of duty and works when needed.
- Full-time and part-time employees whose appointments are for 90 days or more are usually eligible to earn annual leave; intermittent employees are not.
- Seasonal employees work on an annually recurring basis for periods of less than 12 months each year; they may have a full-time, a part-time, or an intermittent schedule during their work season.
- On-call employees work during periods of heavy workload and are in pay status for at least 6 months of each year; they may have either a full-time or a part-time schedule when they are in pay status.

### Block 33 – Part-time Hours Per Biweekly Pay Period

- Indicates the number of hours a part-time employee is scheduled to work during a two-week pay period.

### Block 34 – Position Occupied

- Identifies the employment system under which you are serving — the Competitive Service, the Excepted Service, or the Senior Executive Service (SES).
- The employment system determines your eligibility to move to other jobs in the Federal service, your rights in disciplinary and adverse actions, and your eligibility for reemployment if you leave Federal service.

### Block 35 – FLSA Category

- Exempt employees are not covered by the minimum wage and overtime law (the Fair Labor Standards Act); nonexempt employees are covered.

### Block 37 – Bargaining Unit Status

- Identifies a bargaining unit to which you belong, whether or not you are actually a member of a labor organization. Code "7777" indicates you are eligible but not in a bargaining unit; code "8888" indicates you are ineligible for inclusion in a bargaining unit.

### Blocks 38 and 39 – Duty Station

- Identifies the city, county, and state or the overseas location, where you actually work.

## OTHER INFORMATION

- If your appointment entitles you to elect health benefits or life insurance, and you have not been provided materials explaining the programs available and the enrollment forms, contact your personnel specialist.
- Your personnel specialist will also tell you if your position is covered by an agreement between an employee organization (union) and your agency. If you are eligible to and elect to join an employee organization, you can

elect to have your dues withheld from your salary.

- If you have questions or need more information about your rights and benefits, ask your supervisor or your personnel office.
- Definitions for any coded data in Blocks 1-24, 27-39 and 45-50 may be found in Federal Personnel Manual Supplement 292-1.

It is your responsibility to read all the information on the front of this notice and tell your personnel office immediately if there is an error in it.



TO AVOID DELAY IN PROCESSING:

1. Read the attached information carefully.

2. Typewrite or print in ink.

3. Complete Part A in full. If you are currently a Federal employee, have your employing agency complete Part B.

**A. TO BE COMPLETED BY THE APPLICANT**

1. Name (Last, first, middle)	Andrus, Charles H.	MD		3. Birthdate (mo, dy, yr)	03-28-53
2. List other names you have used	None				
4. Address (Number and street)	545 Gierz Street				
(City, State, and ZIP Code)	Downers Grove, IL 60515				
9. Have you previously filed any application under the Federal Employees Retirement System (FERS) or the Civil Service Retirement System (CSRS)?	<input type="checkbox"/> Yes (Complete items 9a and 9b.)	<input checked="" type="checkbox"/> No			
5. Department or agency in which presently or last employed, including bureau, branch, or division	VA Hines Hospital, Surgical Service		6. Social Security Number	563-94-2723	
7. Location of employment (city and state)	Hines, IL		8. Title of position	Physician	
9a. Type of application	<input type="checkbox"/> Service credit payment	<input type="checkbox"/> Refund	9b. Claim number(s) (if available)		
	<input type="checkbox"/> Return of excess deductions	<input type="checkbox"/> Retirement			

10. List below in chronological order all periods of Federal civilian service. Be sure all your service is listed so that the Office of Personnel Management (OPM) can bill you for the correct amount.

Department or Agency, including bureau, branch or division, where employed	Location of Employment (city and state)	Title of Position	Periods of Service		Check whether deductions were not withheld, withheld and refunded, or withheld and remain to your credit
			Beginning Date	Ending Date	
Veterans Administration	St. Louis, MO	Resident Physician	04-08-82	06-30-86	X
11. Are deductions for the Federal Employees Retirement System now being withheld from your salary?			12. If your answer is "No," give the date of separation from your last position under the Federal Employees Retirement System		Date of separation
<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No					
13. Signature of applicant			14. Telephone number (including area code) where you can be reached during the day		15. Date
<i>Chas. E. Anderson MD</i>			<i>(830) 493-1820</i>		<i>11/16/01</i>

Standard Form 310A  
May 1982

Office of Personnel Management  
5 CFR 842



### B. TO BE COMPLETED BY THE EMPLOYING AGENCY

**INSTRUCTIONS TO THE AGENCY** - Do not use this application to verify service for leave, retention or other non-retirement purposes. The procedures for verifying service for nonretirement purposes or for establishing creditability of service are contained in the Federal Personnel Manual. If more space is needed for the information requested in item 4, please attach a separate sheet. Show the name and Social Security number of the applicant on the separate sheet (SF 3107-1 may be used for this purpose).

1. Is the employee covered by the Federal Employees Retirement System (FERS)?		2. Provide exact date FERS deductions began for the current appointment. (May be before January 1, 1987, if employee was automatically covered by FERS or all of a transferee's service will be credited under FERS rules.)	
<input type="checkbox"/> No	<input checked="" type="checkbox"/> Yes	07-01-86	
3a. Did this employee elect to transfer to FERS? Effective date of election		3b. If yes, is this employee entitled, according to your records, to have part of his/her future retirement annuity computed under CSRS rules?	
<input checked="" type="checkbox"/> No	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Yes

#### 4. CIVILIAN SERVICE NOT UNDER FERS OR CSRS

From verified service documented in official personnel records, list any Federal civilian or District of Columbia Government service not covered by FERS or CSRS deductions which you believe is potentially creditable. If a period of service was subject to another retirement system for Federal employees, note this in the "Leave Without Pay" column. If total basic salary earned for any such period of service is known, a summary entry may be entered on the right-hand side below. Otherwise, show each change affecting basic salary during the period of service. List any period of nondeduction service claimed on the front of this form which cannot be verified from official records and note it in the "Leave Without Pay" column as "Unverified." Service which was not subject to FERS or CSRS deductions is creditable only as specifically allowed by law. NOTE: This information will also be requested on the SF 3107-1 in connection with the employee's retirement. File a copy of this schedule on the right side of the Official Personnel Folder to facilitate completion of the SF 3107-1.

Nature of Action (Appt., pro., res., etc.)	Effective Date (Mo., Day, Year)	Basic Salary Rate	Salary Basis (Per annum, per hour, WAE, etc.)	Leave Without Pay	If Basic Salary actually earned is available make summary entry below		
					From (Mo., Day, Year)	To (Mo., Day, Year)	Total Earned
Exc Appt	04-08-82	\$19,955	PA				
Conv to	07-01-82	\$22,435	"				
Exc Appt							
LWOP	07-01-82	\$22,435	"				
RTD	07-01-83	\$22,435	"				
Conv to	07-01-83	\$23,443	"				
Exc Appt							
Pay Adj	07-01-83	\$25,337	"				
LWOP	10-01-83	\$25,337	"				
Conv to	07-01-84	\$25,020	"				
Exc Appt							
RTD	10-01-84	\$25,020	"				
LWOP	01-01-85	\$25,020	"				
Conv to	07-01-85	\$26,016	"				
Exc Appt							
RTD	01-01-86	\$26,016	"				
LWOP	04-01-86	\$26,016	"				
RTD	07-01-86	\$26,016	"				
Conv to	07-01-86	\$51,835	"				
Exc Appt	(Permanent)						

#### Comments

1983 - LWOP 1/1/83 to 7/1/83; 10/1/83 thru 12/31/83; 3 months excess LWOP  
1984 - LWOP 1/1/84 to 10/1/84; 3 months excess LWOP  
1985 - LWOP 1/1/85 thru 12/31/85; 6 months excess LWOP

\* If part-time, provide the number of hours in the scheduled tour of duty and dates of each change in tour of duty. If employee claims to have worked more than the scheduled tour(s) provide number of hours worked at each pay rate. If intermittent (WAE), provide the number of hours worked, if available, at each pay rate.

**Certification** - The information entered above is based on official records of this agency and is correct. There is no official personnel or fiscal record in this agency of the additional service (if any) alleged by the employee and marked "Unverified" in item 4.

Agency address Edward Hines Jr. VA Hospital Great Lakes HRMS (05) PO Box 5000, Bldg 17 Hines, IL 60141-5000	Signature <i>Elizabeth Dennis</i>	Date 11/16/01
	Official title Human Resources Spec.	Telephone number (708) 202-8387 Ext 21191

PAGE 2 OF 2

NAME: CHARLES H. ANDRUS, MD

DATE: 11-16-2001

REMARKS

\*\*\*\*\*

ESTIMATED DEFERRED RETIREMENT BENEFITS AT AGE 62 WITHOUT  
DEPOSIT MADE FOR TEMPORARY RESIDENCY SERVICE.

PAGE 1 OF 2  
DATE: 11-16-2001

FERS  
PART-TIME  
EMPLOYEE DATA

-----  
EMPLOYEE NAME: CHARLES H. ANDRUS, MD  
DATE OF BIRTH: 03/28/1953  
SERVICE COMPUTATION DATE: 07/01/1986  
DATE OF SEPARATION: 12/31/2001  
DATE OF RETIREMENT: 03/28/2015  
EMPLOYEE'S AGE AT RETIREMENT: 62 YEARS 0 MONTHS  
HIGH-3 SALARY BASED ON DEEMED PAY: \$148,402  
=====

FERS SERVICE CREDIT: 15 YEARS 6 MONTHS 0 DAYS  
== == ==

=====

FERS PART-TIME PRORATION FACTOR: 77.0%

=====

"ESTIMATED"  
DEFERRED RETIREMENT BENEFITS  
-----

	ANNUALLY	MONTHLY
	-----	-----
DEFERRED BASIC ANNUITY:	\$ 17,700.00	\$ 1,475.00
COST OF SURVIVOR BENEFITS:	- 1,764.00	- 147.00
	-----	-----
ESTIMATED NET ANNUITY:	\$ 15,936.00	\$ 1,328.00
	=====	=====
FULL SURVIVING SPOUSE'S ANNUITY:	\$ 8,844.00	\$ 737.00

NAME: CHARLES H. ANDRUS, MD  
DATE: 11-16-2001

"ESTIMATED"  
DEPOSIT FOR SERVICE BETWEEN 04/08/1982 AND 06/30/1986  
-----

=====

CONTRIBUTIONS BASED ON 1.30% OF PAY:	\$	1,344.00
ACCURED INTEREST:		3,576.00
-----		
AMOUNT OF DEPOSIT AS OF 12/31/2001:	\$	4,920.00
=====		

DEPOSIT SERVICE SALARY HISTORY  
-----

SALARY START DATE	SALARY END DATE	ANNUAL SALARY	TOTAL SALARY	REQUIRED CONTRIBUTIONS
-----	-----	-----	-----	-----
04/08/1982	06/30/1982	\$ 19,955.00	\$ 4,601	\$ 59.81
07/01/1982	06/30/1983	22,435.00	22,435	291.65
07/01/1983	06/30/1984	25,337.00	25,337	329.38
07/01/1984	06/30/1985	25,020.00	25,020	325.26
07/01/1985	06/30/1986	26,016.00	26,016	338.21

\*\*\*\*\*  
\*  
\* ! NOTICE !  
\*  
\* IF A DEPOSIT IS NOT MADE AND THE LUMP-SUM ALTERNATIVE FORM OF  
\* ANNUITY (AFA) IS NOT ELECTED, THE SERVICE COVERED BY THE DEPOSIT  
\* CAN NOT BE USED IN COMPUTING RETIREMENT BENEFITS.  
\*  
\*\*\*\*\*

PAGE 2 OF 2  
NAME: CHARLES H. ANDRUS, MD  
DATE: 11-16-2001

REMARKS  
\*\*\*\*\*

ESTIMATED DEFERRED RETIREMENT BENEFITS AT AGE 62 WITH  
DEPOSIT MADE FOR TEMPORARY RESIDENCY SERVICE.

PAGE 1 OF 2  
DATE: 11-16-2001

FERS  
PART-TIME  
EMPLOYEE DATA

-----  
EMPLOYEE NAME: CHARLES H. ANDRUS, MD  
DATE OF BIRTH: 03/28/1953  
SERVICE COMPUTATION DATE: 04/08/1983  
DATE OF SEPARATION: 12/31/2001  
DATE OF RETIREMENT: 03/28/2015  
EMPLOYEE'S AGE AT RETIREMENT: 62 YEARS 0 MONTHS  
HIGH-3 SALARY BASED ON DEEMED PAY: \$148,402  
=====

FERS SERVICE CREDIT: 18 YEARS 8 MONTHS 23 DAYS  
== == ==

=====

FERS PART-TIME PRORATION FACTOR: 81.0%

=====

"ESTIMATED"  
DEFERRED RETIREMENT BENEFITS

-----

	ANNUALLY	MONTHLY
	-----	-----
DEFERRED BASIC ANNUITY:	\$ 22,428.00	\$ 1,869.00
COST OF SURVIVOR BENEFITS:	- 2,244.00	- 187.00
	-----	-----
ESTIMATED NET ANNUITY:	\$ 20,184.00	\$ 1,682.00
	=====	=====
FULL SURVIVING SPOUSE'S ANNUITY:	\$ 11,208.00	\$ 934.00

## *San Joaquin General Hospital*

***P.O. Box 1020 • Stockton, California 95201 • (209) 468-6118***

**CHARLES H. ANDRUS, M.D., F.A.C.S.**  
Vice-Chairman, Department of Surgery  
Associate Director, Surgery Residency Program  
Chief, Surgical Endoscopy

email: candrus@sjgh.hs.co.san-joaquin.ca.us  
Fax #: (209) 468-6246

March 25, 2002

United States Office of Personnel Management  
P.O. Box 952015  
St. Louis, MO 63195-2015

Re: Charles H. Andrus, M.D., F.A.C.S.  
4269 Boulder Creek Court  
Stockton, CA 95219  
(209) 951-0689  
**SSN: 563-94-2723**  
**Claim Number: CSD 7072932**  
DOB: March 28, 1953

Dear Personnel of OPM:

Attached with this letter is my payment of \$1124 and stub to reimburse both deposit and interest to the U.S. Government for my FERS retirement fund for the time of 4/8/82 through 7/1/86. On January 22, 2002, as a direct result of a constructive discharge, I resigned my appointment as a Physician and Surgeon of the Veterans Health Administration of the Department of Veterans Affairs. As you will note above, our family residence has changed and thus I am requesting that my records be changed to reflect this move. Thank you very much for this consideration.

Sincerely,



Charles Andrus, M.D., F.A.C.S.  
A former Surgeon of the VHA of the DVA  
Former Chief of Surgery Services  
Edward Hines, Jr. VAH  
Chicago, IL



UNITED STATES  
**OFFICE OF PERSONNEL MANAGEMENT**  
P.O. BOX 952015  
ST. LOUIS, MO 63195-2015

Claim Number	Date of Birth
CSD 7072932	03/28/1953

ENTER AMOUNT OF THIS PAYMENT \$ <i>1124.00</i>
---

CHARLES H ANDRUS

~~545 GIERZ STREET~~ *4269 Boulder Creek Circle*  
~~DOWNERS GROVE IL 60515~~ *Stockton, CA*  
*95219*

**CIVIL SERVICE DEPOSIT  
ACCOUNT STATEMENT**

NOTE: IF NAME OR ADDRESS IS  
INCORRECTLY PRINTED,  
PLEASE CORRECT IT.

Please detach and return this portion with your payment; see the other side for payment instructions.

STATEMENT OF ACCOUNT—KEEP FOR YOUR RECORDS						
Name	Date	Covered by	Claim Number			
CHARLES H ANDRUS	03/04/2002	FERS	CSD 7072932			
Amount Due	From	To	Type	From	To	Type
Post 9/30/82 Redeposit Interest	.00	04/08/82	07/01/86	F		
Post 9/30/82 Deposit Interest	308.00					
	816.00					
Pre 10/01/82 Redeposit Interest	.00					
	.00					
Pre 10/01/82 Deposit Interest	.00					
	.00					
Less Payments	.00					
Balance Due						
Post 9/30/82 Redeposit	.00					
Post 9/30/82 Deposit	1124.00					
Pre 10/01/82 Redeposit	.00					
Pre 10/01/82 Deposit	.00					
Total	1124.00					

R = Redeposit Period D = Deposit Period

**SEE OTHER SIDE FOR PAYMENT INSTRUCTIONS AND EXPLANATION**

## PAYMENT INSTRUCTIONS

- If you want to make your payment by automatic deduction from a checking or savings account, please complete and return the Authorization for Direct Payments to the Office of Personnel Management, Direct Payment Program, P.O. Box 958241, St. Louis, Missouri 63195-8241. You can obtain this form by calling OPM at 202-606-0708.
- If you are paying by check, please note the amount of your payment on the top portion of this form and return it with your payment to the Office of Personnel Management, P.O. Box 952018, St. Louis, Missouri 63195-2018. Keep the bottom portion; it is your receipt. Do not send correspondence with your payment.
- Make your check, money order, or draft payable to the Office of Personnel Management. Please be sure to write your CSD claim number and date of birth on your check. Do not send cash through the mail.
- You may pay installments of \$50 or more, but paying the full amount now will minimize further interest charges. After each payment we will send you an updated account statement.
- If your address is incorrectly printed, note the corrections on the portion of the form you return with your payment. Or, if you are making payment by an automatic savings or checking account deduction, give us your correct address by calling or writing as indicated below.
- If you have questions about your claim, call us at 1-866-767-6738 or write to the Retirement Operations Center, P.O. Box 45, Boyers, Pennsylvania 16017-0045. To call within the local Washington, DC, area, dial 202-606-0500.

## EXPLANATION OF ACCOUNT STATEMENT

This statement shows the amount of retirement contributions, plus any interest, due the Civil Service Retirement and Disability Fund (CSRDF) for Federal service that is creditable under the Civil Service Retirement System (CSRS) or the Federal Employees Retirement System (FERS). Dates of service are from official records. A redeposit is the repayment of retirement deductions that were withheld from your pay and later refunded to you, plus interest. A deposit is the payment of the retirement deductions that would have been withheld from your pay if you had been employed under CSRS or FERS, plus interest. You are not required to make either of these types of payments. However, the periods of service involved will be used for retirement purposes as described in the following paragraphs.

### FERS SERVICE

- You can make a deposit for creditable FERS service performed before 1989 during which retirement deductions were not withheld from your pay. Interest is charged from the midpoint of periods of service and is compounded annually. Interest is charged to the date the deposit is paid in full or annuity begins, whichever is earlier, and is applied at the rates described in the table below.
- You can also repay any refund you received for any period of civilian service during which retirement deductions were withheld from your pay and later returned to you before you were covered by FERS. Interest is charged from the date of the refund and compounded annually. Interest is charged to the date full payment is made or the date annuity begins, whichever is earlier, and is applied at the rates described in the table below.

If you do not pay for a period of either of these types of service, you will not receive credit in determining your eligibility to retire or in computing your retirement benefit.

actuarial reduction based on the amount of redeposit and interest due and your age at retirement. The actuarial reduction will not be applied to any survivors' annuities. You can avoid the reduction by repaying the refund.

If the refund was paid before October 1, 1982, interest has been charged up through the date of this bill. If full payment is received within 30 days after the bill is issued, no additional interest will be charged. Otherwise, interest will be computed after each payment at the rate of 3% for the interval since the most recent payment.

If the refund was paid on or after October 1, 1982, interest is compounded annually and charged through December 31 of the year before the year in which this bill is being issued. If full payment is received by December 31 of the year in which this bill is issued, no additional interest will be charged. If not, interest will be computed once each year as of December 31 based on the unpaid balance at that time. Interest is applied at the rates described in the table below.

### CSRS SERVICE

- You can make a deposit for creditable CSRS service performed before October 1982 during which retirement deductions were not withheld from your pay. You will receive retirement credit for all of this service whether or not you pay the deposit. But, unless you pay the deposit in full, your annual annuity will be reduced by 10% of the amount of the unpaid balance at retirement. Also, any annuity due your surviving spouse will be reduced proportionately. Interest is charged from the midpoint of periods of service through the date of this bill. If full payment is received within 30 days after the bill is issued, no additional interest will be charged. Otherwise, interest will be computed after each payment at the rate of 3% for the interval since the most recent payment you have made.

- You can make a deposit for creditable CSRS service performed on or after October 1, 1982, during which retirement deductions were not withheld from your pay. Unless you pay the deposit in full, you will not receive credit for the service in your annuity. Interest is charged from the midpoint of periods of service and is compounded annually. Interest is charged through December 31 of the year before the year in which this bill is being issued. If full payment is received by December 31 of the year in which this bill is issued, no additional interest will be charged. If not, interest will be computed once each year as of December 31 based on the unpaid balance at that time. Interest is applied at the rates described in the table below.

- You can repay the refund you received for periods of civilian service ending before October 1990 during which retirement deductions were withheld from your pay and later refunded to you. However, you will receive credit for all of this service whether or not you make the payment (unless you retire under the disability provisions of the law). Your annuity will be subject to permanent

- You can repay the refund you received for periods of civilian service ending on or after October 1, 1990, during which retirement deductions were withheld from your pay and later refunded to you. Unless you pay the redeposit in full, you will not receive credit for this service in the computation of your annuity. Consequently, your annuity, as well as any annuity due your surviving spouse, will be reduced. Interest is compounded annually and charged through December 31 of the year before the year in which this bill is being issued. If full payment is received by December 31 of the year in which this bill is issued, no additional interest will be charged. If not, interest will be computed once each year as of December 31 based on the unpaid balance at that time. Interest is applied at the rates described in the table below.

## INTEREST RATES

Beginning in 1985, interest rates vary each calendar year, according to the interest rates earned by new retirement fund securities. Interest rates through 1999 are:

before 1948	4%	1996	6.875%
1948-1984	3%	1997	6.875%
1985	13%	1998	6.75%
1986	11.125%	1999	5.75%
1987	9%		
1988	8.375%		
1989	9.125%		
1990	8.750%		
1991	8.625%		
1992	8.125%		
1993	7.125%		
1994	6.250%		
1995	7%		

Standard Form 52  
Rev. 7/91  
U.S. Office of Personnel Management  
FPM Supp. 296-33, Subch. 3

## REQUEST FOR PERSONNEL ACTION

### PART A - Requesting Office (Also complete Part B, Items 1, 7-22, 32, 33, 36 and 39.)

1. Actions Requested <b>Resignation</b>		2. Request Number <b>112/943</b>
3. For Additional Information Call (Name and Telephone Number) <b>Tony Chimento X-21691</b>		4. Proposed Effective Date
5. Action Requested By (Typed Name, Title, Signature, and Request Date) <b>Barbara K. Temeck, M.D. Acting Chief, Surgical Service</b>		6. Action Authorized By (Typed Name, Title, Signature, and Concurrence Date) <b>Barbara K. Temeck, M.D. Chief of Staff</b>

### PART B - For Preparation of SF 50 (Use only codes in FPM Supplement 292-1. Show all dates in month-day-year order.)

1. Name (Last, First, Middle) <b>Andrus, Charles H.</b>	2. Social Security Number <b>563-94-2723</b>	3. Date of Birth <b>3/28/53</b>	4. Effective Date <b>1/19/02</b>
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#### FIRST ACTION

5-A. Code	5-B. Nature of Action
5-C. Code	5-D. Legal Authority
5-E. Code	5-F. Legal Authority

#### SECOND ACTION

6-A. Code	6-B. Nature of Action
6-C. Code	6-D. Legal Authority
6-E. Code	6-F. Legal Authority

7. FROM: Position Title and Number <b>Chief, Surgical Service</b>	15. TO: Position Title and Number
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8. Pay Plan	9. Occ. Code	10. Grade or Level	11. Step or Rate	12. Total Salary	13. Pay Basis	16. Pay Plan	17. Occ. Code	18. Grade or Level	19. Step or Rate	20. Total Salary/Award	21. Pay Basis	
12A. Basic Pay	12B. Locality Adj.	12C. Adj. Basic Pay	12D. Other Pay	20A. Basic Pay	20B. Locality Adj.	20C. Adj. Basic Pay	20D. Other Pay					

14. Name and Location of Position's Organization <b>Hines VA Hospital Surgical Service (112) Hines, IL 60141</b>	22. Name and Location of Position's Organization
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#### EMPLOYEE DATA

23. Veterans Preference 1 - None 2 - 5-Point 3 - 10-Point/Disability 4 - 10-Point/Compensable 5 - 10-Point/Other 6 - 10-Point/Compensable/30%	24. Tenure 0 - None 1 - Permanent 2 - Conditional 3 - Indefinite	25. Agency Use	26. Veterans Preference for RIF <input type="checkbox"/> YES <input type="checkbox"/> NO
27. FEGLI	28. Annuitant Indicator	29. Pay Rate Determinant	
30. Retirement Plan	31. Service Comp. Date (Leave)	32. Work Schedule	33. Part-Time Hours Per Biweekly Pay Period

#### POSITION DATA

34. Position Occupied 1 - Competitive Service 2 - Excepted Service 3 - SES General 4 - SES Career Reserved	35. FLSA Category E - Exempt N - Nonexempt	36. Appropriation Code <b>8202:2280</b>	37. Bargaining Unit Status
38. Duty Station Code	39. Duty Station (City - County - State or Overseas Location)		

40. Agency Data	41.	42.	43.	44.	45. Educational Level	46. Year Degree Attained	47. Academic Discipline	48. Functional Class	49. Citizenship 1 - USA 8 - Other	50. Veterans Status	51. Supervisory Status
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### PART C - Reviews and Approvals (Not to be used by requesting office.)

1. Office/Function	Initials/Signature	Date	Office/Function	Initials/Signature	Date
A.			D.		
B.			E.		
C.			F.		

2. Approval: I certify that the information entered on this form is accurate and that the proposed action is in compliance with statutory and regulatory requirements.	Signature	Approval Date
--	-----------	---------------

**PART D - Remarks by Requesting Office**

(Note to Supervisors: Do you know of additional or conflicting reasons for the employee's resignation/retirement?  
If "YES", please state these facts on a separate sheet and attach to SF 52.)

☐ YES ☐ NO

**PART E - Employee Resignation/Retirement**

**Privacy Act Statement**

You are requested to furnish a specific reason for your resignation or retirement and a forwarding address. Your reason may be considered in any future decision regarding your re-employment in the Federal service and may also be used to determine your eligibility for unemployment compensation benefits. Your forwarding address will be used primarily to mail you copies of any documents you should have or any pay or compensation to which you are entitled.

This information is requested under authority of sections 301, 3301, and 8506 of title 5, U.S. Code. Sections 301 and 3301 authorize OPM and agencies to issue

regulations with regard to employment of individuals in the Federal service and their records, while section 8506 requires agencies to furnish the specific reason for termination of Federal service to the Secretary of Labor or a State agency in connection with administration of unemployment compensation programs.

The furnishing of this information is voluntary; however, failure to provide it may result in your not receiving: (1) your copies of those documents you should have; (2) pay or other compensation due you; and (3) any unemployment compensation benefits to which you may be entitled.

1. Reasons for Resignation/Retirement (NOTE: Your reasons are used in determining possible unemployment benefits. Please be specific and avoid generalizations.  
Your resignation/retirement is effective at the end of the day - midnight - unless you specify otherwise.)

2. Effective Date	3. Your Signature	4. Date Signed	5. Forwarding Address (Number, Street, City, State, ZIP Code)
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**PART F - Remarks for SF 50**





Veterans Administration

### EMPLOYEE'S CLEARANCE FROM INDEBTEDNESS

NAME OF EMPLOYEE <b>ANDRUS, Charles, H., M.D.</b>		SOCIAL SECURITY NO. <b>563-94-2723</b>	MAIL FORWARDING ADDRESS <b>4269 Boulder Creek Circle Stockton CA 95219</b>	DATE <b>1/16/2002</b>
TITLE OF POSITION <b>Chief, Surgical Service</b>		STATION NO. <b>578/112</b>	SERVICE, DIVISION AND SECTION <b>Surgical Service (112)</b>	
THE EMPLOYEE IS (Check one) <input checked="" type="checkbox"/> Resignation <input type="checkbox"/> BEING SEPARATED FROM VA <input type="checkbox"/> BEING TRANSFERRED TO (Specify)			THE EMPLOYEE IS (Check one) <input type="checkbox"/> VETERAN <input checked="" type="checkbox"/> NON VETERAN	
			EFFECTIVE DATE <b>1/19/2002</b>	
<i>This certifies that the above-named employee is not indebted to the Government except as noted.</i>				
DEPARTMENTS/STAFF OFFICES	CLEARANCE OFFICIAL	ARTICLES	QTY	UNIT COST
Employee's Service A. Keys B. ADP Coordinator				
Human Resources Mgmt. Service Bldg. 17, (ext 22601)	<i>B. Brooks</i>			
Facilities Mgmt.-Uniform Exchange Bldg. 220, Rm 103, (ext 24819)	<i>Edna Freeman</i>			
Patient Administration Service Bldg 200, Rm B139, (ext 25566)	<i>T. J. Jaks</i>			
Library Service Bldg 1, Rm G100, (ext 22000)				
Medical Media Service Bldg 1, Rm F155, (ext 21074)				
Fiscal Service - Employee Travel Bldg 1, Rm F152, (ext 25566)				
Canteen Service Bldg 45, Rm 109, (ext 22574)	<i>Joiet Buchanan</i>			
Employee Health Bldg 1, Rm E120				
Nutrition & Food Service Bldg 1, Rm E338, (ext 22728)	<i>Joyce Ellison</i>			
Information Resources Mgmt. Bldg 1, Rm G320				
Research Service Bldg 1, Rm C344, (ext 22681)	<i>Mar Hardt</i>			
Credit Union Bldg 1, Rm A133, (ext 22963)	<i>Vanessa Smith</i>			
Security Service Bldg 2, Trailer				
Facilities Management Service Bldg 2, Rm 138, (ext 21135)	<i>Tawana Rogers</i>			
Fiscal Svc - Purchase Card Coord. Bldg 2, 2 <sup>nd</sup> Floor - South				
Materiel Mgmt - IFCAP Coordinator Bldg 2, 2 <sup>nd</sup> Floor, North				
Fiscal Service - Payroll Section Bldg 2, 2 <sup>nd</sup> Floor - North	(MUST BE LAST)			
SHORTAGES NOTED ON VOUCHER NO.		DATE OF VOUCHER		
REMARKS <b>AGREEMENT TO PAY INDEBTEDNESS</b> The Department of Veterans Affairs is hereby authorized to satisfy any portion of remaining indebtedness by withholding any monies due me, including my final salary check, lump-sum annual leave payment, or retirement contributions. SIGNATURE _____ DATE _____				
INSTRUCTIONS: This form must be completed and presented to the Agent Cashier, Finance Division, before final payment will be released.				
SIGNATURE OF APPROVING OFFICIAL	DATE	INITIALS OF AGENT CASHIER	DATE	INDEBTEDNESS COLLECTED
Chief, Fiscal Service				SCHEDULE NO. _____ DATE _____

The employee's service is responsible for initiating VA Form 3248. The employee should be instructed to hand carry this form to the places listed in the order they appear on the form. Areas with extension numbers listed may be cleared by phone. Each service is responsible for carrying out the following:

Employee's Service	- Service clearance (i.e., keys, tools, equipment, etc.) Forwarding address will be typed in applicable block. Prepare for forward a VAF 10-4560 if occupying non-housekeeping or housekeeping quarters to Facilities Mgmt. Service. Attach completed VAF 1301a (in duplicate to VAF 3248. Issue property Pass, GSA Form OF-7, to employee if necessary.
Human Resources Management Service	- Clearance of benefits and records.
Facilities Mgmt. Service - Uniform Exchange	- Collection of uniforms issued. (Note: If no uniforms have been issued, employing unit may delete this step in the clearance process.)
Patient Administration Service - Health Information Mgmt.	- (Physicians & Residents only) Outstanding dictation of hospital discharge summaries, operation reports, and unsigned orders.
Library Service	- Medical Library & Patient Education Resource Center clearance.
Medical Media Service	- Collection of loaned equipment.
Fiscal Service - Employee Travel	- Clearance of outstanding travel claims, travel credit card, and bills of collection.
Canteen Service	- Clearance of Purchase Program payroll deductions and NSF checks.
Employee Health	- Clearance of employees on surveillance programs.
Nutrition & Food Service	- Collection of meal pass.
Information Resources Management Service	- Collection of pagers, cell phones, palm pilots, ADP equipment; deactivation of Outlook & VISTA.
Research Service	- (Employees involved in research activities only) Collection of lab keys and research equipment, clearance of projects.
Credit Union	- Arrangement for outstanding loans.
Security Service	- Collection of photo ID badge and vehicle parking decal.
Facilities Management Service	- Clearance of housekeeping or non-housekeeping quarters and collection of government drivers license.
Fiscal Service - Purchase Card Coordinator	- Collection of Citibank credit card (VISA) and final clearance stop for WOC employees
Materiel Management - IFCAP Coordinator	- Clearance of credit card holder and/or approving official's reconciliations and deactivation.
Fiscal Service - Payroll Section	- Final clearance and processing.

NAME OF EMPLOYEE <b>ANDRUS, Charles, H., M.D.</b>		T & L UNIT <b>086</b>	DIVISION OR SECTION <b>Surgical Service</b>	DATE OF REQUEST <b>1/16/2002</b>
Please deliver salary check as follows: <input checked="" type="checkbox"/> TO BE MAILED  <input type="checkbox"/> TEMPORARY  <input type="checkbox"/> PERMANENT*  <input type="checkbox"/> TO BE CALLED FOR DUE DATE OF CHECK	FOR FINANCE USE ONLY			Authorizations will be effective on the date requested or as soon thereafter as possible.  If to be mailed, type complete name and address on TWO copies. Sign BOTH copies.  If to be delivered to person other than payee, print name of person receiving check on ONE copy.
	DATE OF CHECK	DATE MAILED	*CODED BY DATE	
	TO (Type or print - include ZIP Code) <b>4269 Boulder Creek Circle</b> <b>Stockton, CA</b> <b>95219</b>			
SIGNATURE OF PAYEE		SIGNATURE OF PERSON RECEIVING CHECK (Other than payee)		

VA FORM  
JUN 1993(R)

1301a

\*U.S. Government Printing Office: 1997 - 518-111/83828

**REQUEST FOR DELIVERY OF SALARY CHECK**

NAME OF EMPLOYEE <b>ANDRUS, Charles, H., M.D.</b>		T & L UNIT <b>086</b>	DIVISION OR SECTION <b>Surgical Service</b>	DATE OF REQUEST <b>1/16/2002</b>
Please deliver salary check as follows: <input checked="" type="checkbox"/> TO BE MAILED  <input type="checkbox"/> TEMPORARY  <input type="checkbox"/> PERMANENT*  <input type="checkbox"/> TO BE CALLED FOR DUE DATE OF CHECK	FOR FINANCE USE ONLY			Authorizations will be effective on the date requested or as soon thereafter as possible.  If to be mailed, type complete name and address on TWO copies. Sign BOTH copies.  If to be delivered to person other than payee, print name of person receiving check on ONE copy.
	DATE OF CHECK	DATE MAILED	*CODED BY DATE	
	TO (Type or print - include ZIP Code) <b>4269 Boulder Creek Circle</b> <b>Stockton, CA</b> <b>95219</b>			
SIGNATURE OF PAYEE		SIGNATURE OF PERSON RECEIVING CHECK (Other than payee)		

VA FORM  
JUN 1993(R)

1301a

\*U.S. Government Printing Office: 1997 - 518-111/83828

**REQUEST FOR DELIVERY OF SALARY CHECK**





	From my pay stubs			
	Grade 15			
	Step	Basic pay	Locality adj	Total base pay
2016				
	7	\$ 121,147.00	\$ 143,853.00	\$ 265,000.00
	8			
	9			
	10			
	11			
	12			
	13			
2017				
	7	\$ 121,147.00	\$ 143,853.00	\$ 265,000.00
	8			
	9			
	10			
	11			
	12			
	13			
2018				
	7	\$ 121,147.00	\$ 143,853.00	\$ 265,000.00
	8			
	9			
	10			

		Calculated Annual pay from OHRM posted annual base pay, my step that year, and my locality pay (Column D) for that year								
		Grade 15								
		Step	Basic pay	Locality adj from Column	Total base pay					
	2016		- <a href="https://www.va.gov/OHRM/PAy/2016/PhysicianDentist/PhysicianDentistBaseLongevityRates.pdf">https://www.v a.gov/OHRM/P ay/2016/Physic ianDentist/Phy sicianDentistBa seLongevityRat es.pdf</a>							
		7	\$ 121,147.00							
		8	\$ 124,512.00							
		9	\$ 127,877.00							
		10	\$ 131,242.00	\$ 143,853.00	\$ 275,095.00	August through December 2016	\$ 4,206.25			
		11	\$ 134,607.00							
		12	\$ 137,972.00							
		13	\$ 141,337.00							
	2017		- <a href="https://www.va.gov/OHRM/PAy/2017/PhysicianDentist/PhysicianDentistBaseLongevityRates.pdf">https://www.v a.gov/OHRM/P ay/2017/Physic ianDentist/Phy sicianDentistBa seLongevityRat es.pdf</a>							
		7	\$ 122,361.00							
		8	\$ 125,760.00							
		9	\$ 129,159.00							
		10	\$ 132,558.00	\$ 143,853.00	\$ 276,411.00	January through December 2017	\$ 11,411.00			
		11	\$ 135,957.00							
		12	\$ 139,356.00							
		13	\$ 142,755.00							
	2018		- <a href="https://www.va.gov/OHRM/PAy/2018/PhysicianDentist/PhysicianDentistBaseLongevityRates.pdf">https://www.v a.gov/OHRM/P ay/2018/Physic ianDentist/Phy sicianDentistBa seLongevityRat es.pdf</a>							
		7	\$ 124,077.00							
		8	\$ 127,524.00							
		9	\$ 130,971.00							
		10	\$ 134,418.00	\$ 143,853.00	\$ 278,271.00	January through July 2018	\$ 7,741.42			

	11			
	12			
	13			
2019				
	7	\$ 121,147.00	\$ 143,853.00	\$ 265,000.00
	8			
	9			
	10			
	11			
	12			
	13			
2020				
	7			
	8	\$ 132,671.00	\$ 175,692.00	\$ 308,363.00
	9			
	10			
	11			
	12			
	13			
2021				
	7			
	8			
	9	\$ 137,621.00	\$ 175,692.00	\$ 313,313.00
	10		On my paystubs 75,692 was listed instead of 175,692 which would have given an adjusted basic pay of 216,335	
	11			

		11	\$ 137,865.00	\$ 143,853.00	\$ 281,718.00	August 2018 through December 31, 2018	\$ 6,965.83			
		12	\$ 141,312.00							
		13	\$ 144,759.00							
	2019		- <a href="https://www.va.gov/OHRM/Pay/2019/PhysicianDentist/PhysDentPodBaseL longevityRates.pdf">https://www.va.gov/OHRM/Pay/2019/PhysicianDentist/PhysDentPodBaseL longevityRates.pdf</a>							
		7	\$ 125,813.00							
		8	\$ 129,308.00							
		9	\$ 132,803.00							
		10	\$ 136,298.00							
		11	\$ 139,793.00	\$ 143,853.00	\$ 283,646.00	January through December 2019	\$ 18,646.00			
		12	\$ 143,288.00							
		13	\$ 146,783.00							
	2020		- <a href="https://www.va.gov/OHRM/Pay/2020/PhysicianDentist/PhysDentPodBaseL longevityRates.pdf">https://www.va.gov/OHRM/Pay/2020/PhysicianDentist/PhysDentPodBaseL longevityRates.pdf</a>							
		7	\$ 129,085.00							
		8	\$ 132,671.00							
		9	\$ 136,257.00							
		10	\$ 139,843.00							
		11	\$ 143,429.00	\$ 175,692.00	\$ 319,121.00	January through July 2020	\$ 6,275.50			
		12	\$ 147,015.00	\$ 175,692.00	\$ 322,707.00	August 2020 through December 2020	\$ 5,976.67			
		13	\$ 150,601.00							
	2021		- <a href="https://www.va.gov/OHRM/Pay/2021/PhysicianDentist/PhysDentPodBaseL longevityRates.pdf">https://www.va.gov/OHRM/Pay/2021/PhysicianDentist/PhysDentPodBaseL longevityRates.pdf</a>							
		7	\$ 130,377.00							
		8	\$ 133,999.00							
		9	\$ 137,621.00							
		10	\$ 141,243.00							

	12			
	13			
2022				
	7			
	8			
	9	\$ 140,643.00	\$ 175,692.00	\$ 316,335.00
			On my paystubs \$75,692 was listed instead of \$175,692 which would have given an adjusted basic pay of \$216,335 on the pay stub	
	10	\$ 144,344.00	\$ 175,692.00	\$ 320,036.00
	11		On my paystubs 75,692 was listed instead of 175,692 which would have given an adjusted basic pay of 216,335	
	12			
	13			
		<b>Estimated underpayment from August 2016 to November 2022</b>		
	1st year	Dec 2019 to Nov 2020		
	2nd year	Dec 2020 to Nov 2021		

		11	\$ 144,865.00							
		12	\$ 148,487.00	\$ 175,692.00	\$ 324,179.00	January through December 2021	\$ 10,866.00			
		13	\$ 152,109.00							
	2022									
			- <a href="https://www.va.gov/OHRM/Policy/2022/PhysicianDentist/PhysDentPodBaseLongevityRates.pdf">https://www.va.gov/OHRM/Policy/2022/PhysicianDentist/PhysDentPodBaseLongevityRates.pdf</a>							
		7	\$ 133,241.00							
		8	\$ 136,942.00							
		9	\$ 140,643.00							
		10	\$ 144,344.00							
		11	\$ 148,045.00							
		12	\$ 151,746.00	\$ 175,692.00	\$ 327,438.00	January through July 2022	\$ 6,476.75			
		13	\$ 155,447.00	\$ 175,692.00	\$ 331,139.00	August 2022 through November 3, 2022	\$ 3,701.00			
Just Dec 2019	Cal annual salary					<b>Estimated underpayment by VHA to Dr. Andrus from August 2016 to November 2022</b>	\$ 82,266.42			
1 month / 12	\$ 283,646.00									
			Jan thru Jul 2020	Cal annual salary		Aug thru Nov 2020	Cal annual salary			\$ 317,360.08
		\$ 23,637.17	7 months / 12 months	\$ 319,121.00	\$ 186,153.92	4 months / 12 months	\$ 322,707.00	\$ 107,569.00		
Just Dec	Cal annual salary									



[illegible]

1 month / 12	\$ 322,707.00									
			Jan thru Jul 2021	Cal annual salary		Aug thru Nov 2021	Cal annual salary			\$ 324,056.33
		\$ 26,892.25	7 months / 12 months	\$ 324,179.00	\$ 189,104.42	4 months / 12 months	\$ 324,179.00	\$ 108,059.67		
Just Dec	Cal annual salary									
1 month / 12	\$ 324,179.00									
			Jan thru Jul 2022	Cal annual salary		Aug thru Nov 2022	Cal annual salary			\$ 328,400.08
	Calculated Deemed High-3 Average Salary from the RSSO with returned mail of 2/13/2023 (report date: 01/31/2023)	\$ 27,014.92	7 months / 12 months	\$ 327,438.00	\$ 191,005.50	4 months / 12 months	\$ 331,139.00	\$ 110,379.67		
	<b>Calculated Deemed High-3 Average Salary from this data base</b>									\$ 312,573.00
										\$ 323,272.17
	Unreduced Monthly Annuity from the RSSO with returned mail of 2/13/2023 (report date: 01/31/2023)									
	<b>Calculated Unreduced Monthly Annuity from this data base</b>									\$ 6,337.93
										\$ 6,554.87

0.6 Attachment IV 2023-02-13 VA RSSO 120 SE 6th suite 102 Topeka\_KS e-mail pt 2.pdf



**DEPARTMENT OF VETERANS AFFAIRS**  
Dept. of Veterans Affairs, RSSO  
Townsites Plaza 2  
120 S.E. 6th Ave, Suite 102  
Topeka, KS 66603

Dr. Charles Andrus  
150 Emerald Green Ct.  
St. Louis, MO 63141  
(314) 809-9634

Dear Dr. Andrus:

I wanted to reach out to you and provide a status update on your retirement of 11/3/2022. Your final retirement application passed the 2nd level review check, and our office sent your retirement application to Defense Financial Accounting Services (DFAS) via UPS tracking #1ZA5299A1397126899. DFAS will close out your payroll record, attach your retirement and pay history records, and forward your application to the Office of Personnel Management (OPM).

Included is your final retirement packet just as I sent it to DFAS/OPM. Please retain the retirement packet for your records.

Generally, DFAS will forward your retirement paperwork to OPM the pay period following the one in which you retire. OPM normally issues monthly interim retirement checks for approximately 80% of your net monthly annuity within approximately six to eight weeks of their receipt of your retirement application. Interim monthly annuity payments will continue until OPM has finalized your retirement application and completed their final processing of your monthly annuity.

You should receive a lump-sum payment from the VA for any unused annual leave on your last regular paycheck. TSP will be notified of your retirement approximately 30-45 days after your retirement date. In addition, after speaking with leadership, it was determined to return the documents you have mailed in as they are not pertinent to your salary discrepancy or the retirement.

It has been my pleasure assisting you through this process. Congratulations once again and I wish you a very blessed and Happy Retirement!

Sincerely,

A handwritten signature in cursive script that reads "Dara M. Fairfield".

Dara M. Fairfield





U.S. Department of Veterans Affairs

Workforce Management & Consulting (WMC)  
Retirement Shared Services Office (RSSO)120 SE 6<sup>th</sup> Ave, Suite 102  
Topeka, KS 66603

***Congratulations on your retirement!*** We have processed your retirement application. The attached documents are for your personal file and should be retained as part of your retirement records. Following your retirement date, our office will not receive copies of your retirement information. When you receive information and forms from the Office of Personnel Management (OPM), please keep those with your personal files for future reference.

We have forwarded your application package to the payroll office at the Defense Finance and Accounting Service (DFAS). DFAS will send your final payroll information and retirement package to OPM for adjudication.

**Annual Leave Lump Sum Payment:** If you have annual leave remaining on the date of your retirement, you can normally expect a lump sum payment for that leave on your last paycheck (arriving the Friday after the end the pay period).

**First Retirement Check:** OPM will issue your first interim payment approximately six to eight weeks after receiving your paperwork. Successive interim payments will be received on the first of each month and are a portion of the amount you can expect to receive monthly. When OPM completes the adjudication of your retirement, you will receive a letter explaining your exact monthly annuity amount and your deductions (e.g., health and/or life insurance, taxes, etc., as applicable). While you will not receive a monthly statement, you can expect notification from OPM if the amount of your monthly payment changes for any reason.

**Corresponding with OPM:** Once OPM finalizes your retirement application, they will send you an assigned Civil Service Annuity (CSA) number to reference when you contact OPM. You will also receive a personal identification number (PIN) which will allow you to make changes online at <https://www.servicesonline.opm.gov>. After your retirement, please contact OPM to make any updates (e.g., change of address, tax withholding, direct deposit changes).

**Health Benefits:** If you are eligible for health benefits after retirement, your current coverage will continue and deductions will be made from your monthly annuity check. You will be eligible to make changes to your coverage during Federal Benefits Open Season (Monday of the second full workweek in November through the Monday of the second full workweek in December). OPM will provide you with information and instructions.

**Life Insurance:** If you were eligible to continue life insurance into retirement, your election has been sent to OPM with your retirement package. Please contact OPM to make changes to your life insurance coverage.

**Thrift Savings Plan (TSP):** DFAS will notify TSP about your separation, usually about 30 days after your retirement has been processed. Before making decisions regarding your TSP account, you should carefully review the enclosed TSP information. The TSP Website ([www.tsp.gov](http://www.tsp.gov)) contains valuable information including calculators and necessary forms. You must be separated from federal service for 31 or more days to be eligible for a post-employment withdrawal. It is important to keep TSP informed of any address changes after retirement by using Form TSP-9, Change in Address for Separated Participants. Send TSP forms to the address on the form; do not send TSP forms to the RSSO.

Going forward, OPM is your first point of contact for questions regarding your retirement or to make changes to your retirement records. OPM's number is 1-888-767-6738; it is answered from 7:40 a.m. to 5:00 p.m. (ET). OPM's website at [www.opm.gov/retire](http://www.opm.gov/retire) provides additional information regarding your retirement benefits.





## Certified Summary of Federal Service

### Federal Employees Retirement System

Office of Personnel  
Management  
5 CFR Part 841

#### Information for the Agency

1. A certified copy of this form must accompany the employee's *Application for Immediate Retirement* (SF 3107).
2. This form may also be used:
  - for retirement counseling purposes
  - to respond to an employee's request for a record of creditable service
3. See the CSRS and FERS Handbook for Personnel and Payroll Offices for detailed instructions for completion and disposition of this form.

#### Instructions for the Employee

1. Your employing office will complete and certify this form for you.
2. Review this form carefully. Be sure it contains all of your service.
3. Complete Section E, Employee's Certification, and return the form to your employing office.

#### Section A - Identification

1. Name of employee ( <i>last, first, middle</i> ) ANDRUS, CHARLES, H	2. Date of birth ( <i>mm/dd/yyyy</i> ) 3/28/1953	3. Social Security Number 563-94-2723
4. List all other names used ( <i>maiden name, AKA, spelling variants</i> )	5. Other birth dates used	6. Military serial number
7. Service computation date for retirement purposes 10/25/1996		
8a. Did this employee elect to transfer to FERS?  <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes, give effective date of election:	8b. If the employee elected to transfer to FERS, is the employee entitled, according to your records, to have part of the FERS annuity computed under CSRS rules?  <input type="checkbox"/> Yes <input type="checkbox"/> No	
9a. Does the applicant receive military retired pay?  <input type="checkbox"/> Yes ( <i>Attach a copy of the applicant's military retired pay order, if available, and complete 9b.</i> ) <input checked="" type="checkbox"/> No	9b. If yes, has the applicant waived military retired pay to credit military service for FERS retirement?  <input type="checkbox"/> Yes ( <i>Attach a copy of the military finance center's letter to the employee accepting waiver, if available.</i> ) <input type="checkbox"/> No ( <i>Include cases where a waiver is not necessary.</i> )	

#### Section B - Verified Service History Documented in Official Personnel Records

Federal agency or military service branch	Appointment, separation, or conversion dates for civilian and active honorable military service		Name of retirement system*	Remarks and non-creditable time**
	From (mm/dd/yyyy)	To (mm/dd/yyyy)		
Department of Veterans Affairs	04/08/1982	09/30/1982	FICA Only	Deposit Paid
Department of Veterans Affairs	10/01/1982	06/30/1986	FICA Only	Deposit Paid
Department of Veterans Affairs	07/01/1986	12/31/1986	CSRS Offset	07/01/1986 to 12/31/1986 PT Actual Hours: 827
Department of Veterans Affairs	01/01/1987	01/19/2002	FERS	01/01/1987 to 12/31/1987 PT Actual Hours: 962 01/01/1988 to 12/31/1988 PT Actual Hours: 1820 01/01/1989 to 12/31/1989 PT Actual Hours: 1820 01/01/1990 to 12/31/1990 PT Actual Hours: 1762 01/01/1991 to 12/31/1991 PT Actual Hours: 1281 01/01/1992 to 12/31/1992 PT Actual Hours: 1303 01/01/1993 to 12/31/1993 PT Actual Hours: 1336 01/01/1994 to 12/31/1994 PT Actual Hours: 1275 01/01/1995 to 12/31/1995 PT Actual Hours: 1250 01/01/1996 to 12/31/1996 PT Actual Hours: 1385 01/01/1997 to 12/31/1997 PT Actual Hours: 1565 01/01/1998 to 12/31/1998 PT Actual Hours: 1827 01/01/1999 to 12/31/1999 PT Actual Hours: 1823 01/01/2000 to 12/31/2000 PT Actual Hours: 1820 01/01/2001 to 12/31/2001 PT Actual Hours: 1828 01/01/2002 to 01/19/2002 Biweekly TOC: 70
Department of Veterans Affairs	08/07/2016	11/3/2022	FERS	VOLUNTARY RETIREMENT

\* Give details of creditable civilian service not subject to retirement deductions in Section C.

\*\*In Remarks, show if CSRS service on or after January 1, 1984, is "regular" CSRS or CSRS Offset. Indicate if service is part-time. If service was performed on a WAE or intermittent basis, show the number of days worked in "Remarks." If the number of days worked is not available, then show the number of hours worked.

### Federal Employees

Service which is not subject to FERS or CSRS deductions is creditable only as specifically allowed by law.

Nature of action (Appt., pro., res., etc.)	Effective date (mm/dd/yyyy)	Basic salary rate	Salary basis (per annum, per hour, WAE, etc.)	Leave without pay	If basic salary actually earned is available make summary entry below		
					From (mm/dd/yyyy)	To (mm/dd/yyyy)	Total earned

## Section D - Agency Certification

I certify that the information on this form accurately reflects verified information contained in official records and that the applicant has sufficient service to be entitled to an annuity. I further certify that all required documentation in support of this application is attached, accurate and complete.

Signature of authorized agency personnel official

Agency name and address, including ZIP Code, telephone number (including area code), FAX number, and EMAIL address

Department of Veterans Affairs-RSSO  
120 SE 6th Ave. Ste. 102  
Topeka, KS 66603  
785-350-1553  
Fax: 785-228-4813  
dara.fairfield@va.gov

Official Title

Date (mm dd yyyy)

Human Resources Specialist

1/29/2023

### Section E - Employee's Certification

☒ The service listed is complete.

☐ I have additional service. (If you claim additional service, attach signed statement(s) giving dates, positions, titles and locations of employment, including agency, bureau, and division. Claimed service cannot be credited for retirement until it has been verified. This includes unverified service listed on an SF 144, *Statement of Prior Federal Civilian and Military Service*, or similar affidavit.)

Note: If you have performed Federal civilian service subject to social security deductions (FICA) or not subject to retirement deductions, be sure that your agency has correctly completed Section C above.

Signature (do not print)

Date (mm/dd/yyyy)

1/29/2023





## Agency Checklist of Immediate Retirement Procedures

### Federal Employees Retirement System

#### Section A - Employing Office Checklist: To be completed by office maintaining Official Personnel Folder (OPF).

1. Name (last, first, middle)  ANDRUS, CHARLES, H	2. Date of birth (mm/dd/yyyy)  03/28/1953	3. Social Security Number  563-94-2723																																						
4. Type of retirement <input checked="" type="checkbox"/> Immediate Voluntary (MRA+30, 60+20, 62+5) <input type="checkbox"/> Immediate Voluntary (MRA+10 with age reduction) <input type="checkbox"/> Early Retirement (Major RIF, reorganization, or transfer of function) <input type="checkbox"/> Involuntary Retirement <input type="checkbox"/> Disability	5. Special provisions (Check any applicable) <input type="checkbox"/> 25 Years Law Enforcement/Firefighter <input type="checkbox"/> 20 Years Law Enforcement/Firefighter and age 50 <input type="checkbox"/> 25 Years Air Traffic Controller <input type="checkbox"/> 20 Years Air Traffic Controller and age 50 <input type="checkbox"/> Other: _____																																							
6. Pay Plan and Occupational Series Code at Retirement  <div style="text-align: center;">VM 0602</div>																																								
7. Is the applicant eligible to continue health benefits coverage into retirement? <input checked="" type="checkbox"/> Yes, enrollment code: <u>106</u> <input type="checkbox"/> No, give reason: _____																																								
8. Does the applicant meet the requirements for the continuation of life insurance into retirement? <input checked="" type="checkbox"/> Yes, complete 8a. <input type="checkbox"/> No, give reason: _____																																								
8a. The applicant can continue Basic Life insurance and the following options: <input checked="" type="checkbox"/> No optional insurance <input type="checkbox"/> Option A - Standard <input type="checkbox"/> Option B - Additional with the following multiples of pay: <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5 <input type="checkbox"/> Option C - Family with the following multiples of pay: <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> 5																																								
9. Are the following documents attached or actions taken? Indicate by an "X" for each item.		<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 50%;">Attached</th> <th style="width: 50%;">Not Applicable</th> </tr> </thead> <tbody> <tr><td style="text-align: center;">✓</td><td></td></tr> <tr><td style="text-align: center;">✓</td><td></td></tr> <tr><td></td><td style="text-align: center;">✓</td></tr> <tr><td style="text-align: center;">✓</td><td></td></tr> <tr><td></td><td style="text-align: center;">✓</td></tr> <tr><td></td><td></td></tr> <tr><td style="text-align: center;">✓</td><td></td></tr> <tr><td></td><td style="text-align: center;">✓</td></tr> <tr><td></td><td style="text-align: center;">✓</td></tr> <tr><td></td><td style="text-align: center;">✓</td></tr> <tr><td></td><td style="text-align: center;">✓</td></tr> <tr><td></td><td style="text-align: center;">✓</td></tr> <tr><td></td><td style="text-align: center;">✓</td></tr> <tr><td></td><td style="text-align: center;">✓</td></tr> <tr><td></td><td style="text-align: center;">✓</td></tr> <tr><td></td><td style="text-align: center;">✓</td></tr> <tr><td></td><td style="text-align: center;">✓</td></tr> <tr><td></td><td style="text-align: center;">✓</td></tr> </tbody> </table>	Attached	Not Applicable	✓		✓			✓	✓			✓			✓			✓		✓		✓		✓		✓		✓		✓		✓		✓		✓		✓
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a. SF 3107* b. All documents applicant shows as attached to SF 3107 c. If applicant is married and elects less than the maximum survivor benefit, SF 3107-2* d. SF 3107-1* e. If discontinued service retirement, documentation specified in Chapter 44, CSRS/FERS Handbook for Personnel and Payroll Offices, including OPM Form 1510* and attachments, if available. f. If early retirement, enter OPM Authority Number here _____ g. Agency estimate of benefits, if prepared. h. If applicant has military service, DD 214 or its equivalent, if available i. If applicant wants to waive military retired pay, copy of waiver request and response from Military Retired Pay Center, if available j. If applicant served in the military, or applied for military retired pay or DOVA benefits in lieu of military retired pay, or applied for OWCP benefits, Schedules A, B, C of SF 3107. k. If applicant wants a refund of military service deposit because he/she does not want to waive military retired pay, SF 3106* l. If post-1956 military service deposit is not made, was applicant counseled about the effects of not paying the deposit? <input type="checkbox"/> Yes <input type="checkbox"/> No (See OPM Form 1515*) m. If applicant wants Federal Income tax withheld at the same rate as while an employee, copy of W-4 form on file with your agency. n. If the annuitant meets the 5-year requirement to continue health benefits into retirement based on previous coverage as a family member under someone else's FEHB plan or prior coverage under the Uniformed Services Health Benefits Program, attach documentation. o. If a court order requires the annuitant to provide mandatory self and family FEHB coverage for his/her children under P.L. 106-394, a copy of the court order. p. If law enforcement officer/firefighter/air traffic controller/Customs and Border Protection Officer/Nuclear Materials Courier, agency certification of service that makes the applicant eligible for an enhanced annuity benefit. q. If employee has applied for compensation benefits, OWCP award, if available																																								
10. If the type of annuity is <b>not</b> disability, are the following documents attached? (Mark "X" in appropriate column.)																																								
<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 30%;"></th> <th style="width: 10%;">Attached</th> <th style="width: 10%;">Not Applicable</th> <th style="width: 10%;">Sent to OWCP</th> </tr> </thead> <tbody> <tr><td>a. All SF 2809's* in the applicant's OPF</td><td style="text-align: center;">✓</td><td></td><td></td></tr> <tr><td>b. All SF 2810's* in applicant's OPF</td><td></td><td style="text-align: center;">✓</td><td></td></tr> <tr><td>c. SF 2821*</td><td style="text-align: center;">✓</td><td></td><td></td></tr> <tr><td>d. SF 2818*</td><td style="text-align: center;">✓</td><td></td><td></td></tr> </tbody> </table>		Attached	Not Applicable	Sent to OWCP	a. All SF 2809's* in the applicant's OPF	✓			b. All SF 2810's* in applicant's OPF		✓		c. SF 2821*	✓			d. SF 2818*	✓			<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 30%;"></th> <th style="width: 10%;">Attached</th> <th style="width: 10%;">Not Applicable</th> </tr> </thead> <tbody> <tr><td>e. All SF 54's* &amp; SF 2823's* in the applicant's OPF</td><td style="text-align: center;">✓</td><td></td></tr> <tr><td>f. All SF 2817's*, SF 176's*, SF 176T's*</td><td style="text-align: center;">✓</td><td></td></tr> <tr><td>g. All SF 3102's*</td><td></td><td style="text-align: center;">✓</td></tr> <tr><td>h. RI 76-10*, if applicable</td><td></td><td style="text-align: center;">✓</td></tr> </tbody> </table>			Attached	Not Applicable	e. All SF 54's* & SF 2823's* in the applicant's OPF	✓		f. All SF 2817's*, SF 176's*, SF 176T's*	✓		g. All SF 3102's*		✓	h. RI 76-10*, if applicable		✓			
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g. All SF 3102's*		✓																																						
h. RI 76-10*, if applicable		✓																																						
11. If the type of retirement is disability, is the employee's disability documentation specified in SF 3112* attached? <input type="checkbox"/> Yes <input type="checkbox"/> No, explain: _____																																								



12. List any documents which are attached, but not listed above:

FEHB Transfer Out Memo, W-4P, Marriage certificate, SF2819, SF50 in lieu of 2817, FICA SF50s, Memo to OPM, Misc. documents for salary proof, awards, VA letter CSD Account Statement, FEGLI report

13. Certification by Chief Personnel Officer or Designee - *I certify that the above accurately reflects verified information in official records and that the applicant has sufficient service to support title to an annuity. I further certify that all required documentation in support of this application is attached, accurate and complete.*

Signature (do not print)

*Dara M. Fairfield*

Address

Department of Veterans Affairs  
Townsite Plaza #2, 120 SE 6th Ave.  
Suite 102  
Topeka, KS 66603 3515

Official Title

HR Specialist

Person to contact for further information

Dara M. Fairfield

Submitting Office Number (SON)

1250

Email address

dara.fairfield@va.gov

Telephone number

(866) 330-7366

FAX number

785-228-4813

**Offenses Barring Annuity Payments:** Public Law 87-299 prohibits payment of annuity to persons who have committed specified offenses involving the national security of the United States. Employing agencies are responsible for submitting all pertinent information to the Office of Personnel Management, Retirement Services, in any case when this law possibly applies.

**Section B - Payroll Office Checklist:** To be completed by the office maintaining the Individual Retirement Record  
(SF 3100\* and SF 3100A\*)

**Important:** The SF 3100 or SF 3100A for applicant must be closed out and sent to OPM no later than 30 days after the pay date of the final paycheck.

	Yes	No**
1. Does the SF 3100 or SF 3100A for the applicant named in Section A contain all information necessary to comply with OPM instructions for maintaining the Individual Retirement Record?		
2. Is his or her sick leave balance as of retirement shown on SF 3100 or SF 3100A?		
3a. Is the applicant someone who elected to transfer to FERS and who is entitled to have a portion of his or her benefits computed under CSRS rules?		
3b. If yes, are his or her sick leave balances at the time of transfer and as of retirement shown on SF 3100 or SF 3100A?		
4. Is applicant's last day in pay status shown on SF 3100 or SF 3100A?		
5. Is applicant's health benefits status posted on SF 3100 or SF 3100A?		
6. If this is a preliminary SF 3100 or SF 3100A for disability retirement, is applicant's life insurance status posted?		
7. If applicant is continuing life insurance into retirement, is the SF 2821 with Payroll Office certifying signature attached?		
8a. Has applicant made a military service deposit with your agency?		
8b. If yes, is an SF 3100 or SF 2806* for the deposit attached?		
9a. Does the applicant have any part-time service (for an employee who elected to transfer to FERS and is eligible to have a portion of his/her annuity computed under CSRS rules, any part-time service on or after April 7, 1986)?		
9b. If yes, is the number of hours in each scheduled tour of duty and the date of each change in tour of duty posted on the SF 3100 or SF 3100A (including changes to full-time and intermittent status)? If the employee worked in excess of his/her scheduled tour of duty, post the actual earnings or hours actually worked at each rate of pay.		
10. If the applicant is a postal employee, are postal earnings for non-deduction service shown on SF 3100?		
11. Disposition of SF 3100 or SF 3100A: SF 3100 or SF 3100A and Register of Separations and Transfers (SF 3103) are attached***. If SF 3100 or SF 3100A was already forwarded, provide the following:		
Forwarded to:	SF 3103 number	Date (mm/dd/yyyy) of SF 3103

\* See page 3 of 3 for titles of forms referred to above.

\*\* Explain any "No" responses in item 12 on the next page.

\*\*\*Employees who elected to transfer to FERS may have a redesignated SF 2806 instead of, or in addition to SF 3100 or SF 3100A.



\*12. Explain any "No" responses here:

13. Certification by the Chief Payroll Officer or Designee

***I certify that the above reflects official records maintained by this office.***

Signature (do not print)

Telephone number

FAX number

Payroll Office Number

Date (mm/dd/yyyy)

Email address

97381600

***Titles of Forms Referred to in Sections A & B:***

SF 2806	Individual Retirement Record (CSRS)	SF 3103	Register of Separations and Transfers
SF 2809	Employee Health Benefits Election Form	SF 3106	Application for Refund of Retirement Deductions
SF 2810	Notice of Change in Health Benefits Enrollment	SF 3107	Application for Immediate Retirement (FERS)
SF 176, SF 176T, & SF 2817	Life Insurance Election	SF 3107-1	Certified Summary of Federal Service
SF 2818	Continuation of Life Insurance Coverage As an Annuitant or Compensation	SF 3107-2	Spouse's Consent to Survivor Election
SF 2821	Agency Certification of Insurance Status	SF 3112	Documentation in Support of Disability Retirement
SF 54 & SF 2823	Life Insurance Designation of Beneficiary	OPM Form 1510	Cert. of Agency Offer of Position and Required Doc.
SF 3100	Individual Retirement Record (FERS)	OPM Form 1515	Military Service Deposit Election
SF 3100A	Individual Retirement Record (FERS)	RI 76-10	Assignment FEGLI Program
SF 3102	FERS Designation of Beneficiary	DD 214	Certificate of Release or Discharge from Active Duty

Department of  
Veterans Affairs

# Memorandum

Date: 1/31/2023

From: Dara Fairfield, HR Specialist (Retirements)  
VHA – Retirement Shared Services Office; Topeka, KS

Subj: Transfer Out of Health Insurance

To: OPM, Bureau of Retirement & Insurance, Washington, DC 20415

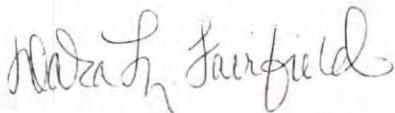
Reference:

Employee Name:	Charles H. Andrus
Employee SSN:	563-94-2723
Retirement Date:	11/3/2023
FEHB Plan	Blue Cross & Blue Shield
FEHB Plan Enrollment Code:	106

1. As specified in the Federal Employees Health Benefits Handbook, attached are copies of the SF 2809s and SF 2810s from the employee's Official Personnel Folder beginning with the date of his or her initial enrollment in the FEHB Program and any related documentation (such as medical documentation for a disabled child over age 26).
2. Additional Pertinent Information: **None.**
3. If there are questions regarding this information, please contact:

Specialist Name:	Dara Fairfield
Specialist Phone Number:	785-350-1553
Specialist Mailing Address	DEPARTMENT OF VETERANS AFFAIRS (VHA-RSSO) 120 SE 6TH AVE., STE. #102 Townsite Plaza II TOPEKA, KS 66603-3515

Regards,



Human Resources Specialist



RECEIVED 04/28/2011 05:22

From: VA

314 289 7034

08/31/2016 14:57

#341 P.002/007

YD 00431352



Federal Employees  
Health Benefits Program

### Health Benefits Election Form

Form Approved  
OMB No. 3206-0180

**Part A - Enrollee and Family Member Information (For additional family members use a separate sheet and attach.)**

1 Enrollee name (last, first, middle initial) <u>Andrus Charles H</u>	2 Social Security number <u>563-94-2723</u>	3 Date of birth (mm/dd/yyyy) <u>03/28/1953</u>	4 Sex <input checked="" type="checkbox"/> M <input type="checkbox"/> F	5 Are you married? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
6 Home mailing address (including ZIP Code) <u>150 Emerald Green Ct</u> <u>St. Louis MO 63141</u>		7 If you are covered by Medicare, check all that apply <input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> D		8 Medicare Claim Number
9 Are you covered by insurance other than Medicare? <input checked="" type="checkbox"/> Yes, indicate in item 10 below <input type="checkbox"/> No				

10 Indicate the type(s) of other insurance  
☐ TRICARE ☒ Other Name of other insurance: \_\_\_\_\_ Policy number: \_\_\_\_\_

☐ FEHB An FEHB self and family enrollment covers all eligible family members. No person may be covered under more than one FEHB enrollment. See instructions for item 10 on page 1.

11 Name of family member (last, first, middle initial) <u>Andrus Pamela B</u>	12 Social Security number <u>522-04-5324</u>	13 Date of birth (mm/dd/yyyy) <u>04/30/1959</u>	14 Sex <input type="checkbox"/> M <input checked="" type="checkbox"/> F	15 Relationship code
16 Address (if different from enrollee) _____		17 If this family member is covered by Medicare, check all that apply <input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> D		18 Medicare Claim Number
19 Is this family member covered by insurance other than Medicare? <input checked="" type="checkbox"/> Yes, indicate in item 20 below <input type="checkbox"/> No				

20 Indicate the type(s) of other insurance  
☐ TRICARE ☒ Other Same as United Healthcare Policy number (80840) 911-87726-04

☐ FEHB An FEHB self and family enrollment covers all eligible family members. No person may be covered under more than one FEHB enrollment. See instructions for item 10 on page 1.

21 Email address (if home address is different from enrollee's) <u>candrus600@aol.com</u>	22 Preferred telephone number (if home address is different from enrollee's)			
23 Name of family member (last, first, middle initial)	24 Social Security number	25 Date of birth (mm/dd/yyyy)	26 Sex <input type="checkbox"/> M <input type="checkbox"/> F	27 Relationship code
28 Address (if different from enrollee) _____		29 If this family member is covered by Medicare, check all that apply <input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> D		30 Medicare Claim Number
31 Is this family member covered by insurance other than Medicare? <input type="checkbox"/> Yes, indicate in item 32 below <input type="checkbox"/> No				

32 Indicate the type(s) of other insurance  
☐ TRICARE ☐ Other Name of other insurance: \_\_\_\_\_ Policy number: \_\_\_\_\_

☐ FEHB An FEHB self and family enrollment covers all eligible family members. No person may be covered under more than one FEHB enrollment. See instructions for item 10 on page 1.

33 Email address (if home address is different from enrollee's)	34 Preferred telephone number (if home address is different from enrollee's)			
35 Name of family member (last, first, middle initial)	36 Social Security number	37 Date of birth (mm/dd/yyyy)	38 Sex <input type="checkbox"/> M <input type="checkbox"/> F	39 Relationship code
40 Address (if different from enrollee) _____		41 If this family member is covered by Medicare, check all that apply <input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> D		42 Medicare Claim Number
43 Is this family member covered by insurance other than Medicare? <input type="checkbox"/> Yes, indicate in item 44 below <input type="checkbox"/> No				

44 Indicate the type(s) of other insurance  
☐ TRICARE ☐ Other Name of other insurance: \_\_\_\_\_ Policy number: \_\_\_\_\_

☐ FEHB An FEHB self and family enrollment covers all eligible family members. No person may be covered under more than one FEHB enrollment. See instructions for item 10 on page 1.

45 Email address (if home address is different from enrollee's)	46 Preferred telephone number (if home address is different from enrollee's)			
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RECEIVED 04/28/2011 05:22

From:VA

314 289 7034

06/31/2016 14:58

#341 P.003/007

**Part B - FEHB Plan You Are Currently Enrolled In (if applicable)**

1 Plan name 2 Enrollment code

**Part D - Event That Permits You To Enroll, Change, or Cancel (see page 2)**

1 Event code 2 Date of event  
1A 08/08/2016

**Part F - Cancellation of FEHB**

☐ I CANCEL my enrollment.  
My signature in Part H certifies that I have read and understand the information on page 3 regarding cancellation of enrollment.

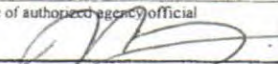
**Part H - Signature**

**WARNING:** Any intentionally false statement in this application or willful misrepresentation relative thereto is a violation of the law punishable by a fine of not more than \$10,000 or imprisonment of not more than 5 years, or both. (18 U.S.C. 1001.)

1 Your signature (do not print)  
Charles H Andrus MD  
2 Email address  
andrusmd@slu.edu

2 Date (mm/dd/yyyy)  
08/25/2016  
4 Preferred telephone number  
(314) 991-2274

**Part I - To be completed by agency or retirement system**  
**REMARKS**

1 Date received (mm/dd/yyyy) 09/01/2016	2 Effective date of action (mm/dd/yyyy) 09/04/2016	3 Personnel telephone number ( ) 314-894-6620
4 Name and address of agency or retirement system VA ST. LOUIS HEALTH CARE SYSTEM #1 JEFFERSON BARRACKS DRIVE ST. LOUIS, MO 63125		5 Authorizing official (please print) Denise Busuk 6 Signature of authorized agency official 
7 Payroll office number 9738 1600	8 Payroll office contact (please print) DEBORA HALL	9 Payroll telephone number ( ) 913-758-6445

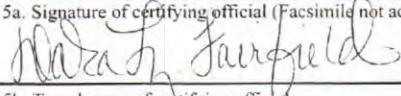
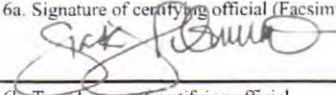


## Agency Certification of Insurance Status

### Federal Employees' Group Life Insurance Program

Federal Employees  
Group Life Insurance

**To Agency: See reverse for information and instructions**

1. Name of employee (Last, first, middle) <b>ANDRUS, CHARLES, H</b>		2. Date of birth (Month, day, year) <b>03/28/1953</b>		3. Social Security number <b>563-94-2723</b>	
4a. Event requiring certification <input type="checkbox"/> Separation (includes resignation) <input checked="" type="checkbox"/> Retirement <input type="checkbox"/> Death as an employee Had employee filed Application for Retirement (SF 2801 or SF 3107) with OPM? <div style="display: flex; justify-content: space-around;"><input type="checkbox"/> No <input type="checkbox"/> Yes</div> <input type="checkbox"/> Death as a reemployed annuitant <input type="checkbox"/> End of 12 months non-pay status <input type="checkbox"/> Other (Specify)		4b. Employee's retirement system <input checked="" type="checkbox"/> CSRS/FERS <input type="checkbox"/> CIA <input type="checkbox"/> Other (Specify) <input type="checkbox"/> TVA <input type="checkbox"/> FICA <input type="checkbox"/> DCRS* <input type="checkbox"/> FRSR *D.C. Police & Fire/Public School Teachers		5. Disposition of Designations of Beneficiary (SF 54, SF 2823) <input checked="" type="checkbox"/> Attached <input type="checkbox"/> None on file with this agency <input type="checkbox"/> On file in employee's Official Personnel Folder	
		4c. OWCP number (if applicable)			
		6. Did the employee assign his/her insurance? <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes (attach RI 76-10)		7. Did the employee elect living benefits? Amount elected (check one and attach EOB) <div style="display: flex; justify-content: space-between;"><input checked="" type="checkbox"/> No <input type="checkbox"/> Partial (post-election BIA \$ _____) <input type="checkbox"/> Yes <input type="checkbox"/> Full</div>	
8. Date of event checked in item 4a <b>11/3/2022</b>		9. Date of SF 2819, Notice of Conversion Privilege - <b>Issuance Is Mandatory</b> (Prepare SF 2819 for each employee whose coverage as an employee terminates, including all retiring employees) <b>1/29/2023</b>			
10. Annual basic pay (not basic insurance amount) on date in item 8 (Convert hourly, daily, piecework, etc., rate to annual rate) <b>\$320,036</b>		11. Effective date of continuous coverage under the FEGLI Program (If any break in service, list dates) <b>8/7/2016</b>			
12a. Did employee have Option A - Standard Insurance on date in item 8? <div style="display: flex; align-items: center;"><input checked="" type="checkbox"/> No <input type="checkbox"/> Yes</div>		12b. Amount of Option A		13a. Did employee have Option C - Family Insurance on date in item 8? <div style="display: flex; align-items: center;"><input checked="" type="checkbox"/> No <input type="checkbox"/> Yes</div>	
		12c. Effective date of election		13b. Effective date of election	
14a. Did employee have Option B - Additional Insurance on date in item 8? <div style="display: flex; align-items: center;"><input checked="" type="checkbox"/> No <input type="checkbox"/> Yes</div>		14b. Effective date of election		14c. Number of multiples on date in item 8	
				14d. Lowest number of multiples during last 5 years	
<b>15. Personnel records certification (This form will not be accepted without both personnel and payroll certification.)</b> I certify that the above information was obtained from, and correctly reflects, official personnel records, and that the employee was covered by Federal Employee's Group Life Insurance on the date in item 8.					
15a. Signature of certifying official (Facsimile not acceptable) 			15e. Name and address of agency (Including ZIP Code) <b>Department of Veterans Affairs-RSSO 120 SE 6th Ave. Ste. 102 Topeka, KS 66603 866-330-7366 Fax: 785-228-4813 vharssso@va.gov</b>		
15b. Typed name of certifying official <b>Dara M. Fairfield</b>					
15c. Title <b>Human Resources Specialist</b>					
15d. Date <b>1/31/2023</b>			15f. Telephone number (Including area code) <b>(866) 330-7366</b>		
<b>16. Payroll records certification (This form will not be accepted without dual certification.)</b> I certify that I have compared the annual basic pay shown in item 10, above, with current payroll records and the figures agree. Payroll deductions were being made or would have been made if the employee had been in pay status for the alpha code (Insurance code and SF 50 equivalent) on the date in the item 8.					
					Alpha code <b>C0</b>
16a. Signature of certifying official (Facsimile not acceptable) 			16f. Name and address of payroll office (If different from that given in item 15e) <b>Defense Finance &amp; Accounting Service DFAS-IN-JFVBBA 8899 East 56th ST Indianapolis, IN 46249 6200</b>		
16b. Typed name of certifying official <b>Sianna Palomo</b>					
16c. Title <b>Lead Human Resources Specialist</b>					
16d. Date <b>1/31/2023</b>		16e. Telephone number (Including area code) <b>(866) 330-7366</b>		16g. Payroll office number <b>97381600</b>	
Remarks (For agency use only)			OPM use only		

**PART 1 - Original**





**Continuation of Life Insurance Coverage**  
*As an Annuitant or Compensation*  
Federal Employees' Group Life Insurance (FEGLI) Program

**Important:**  
Read instructions on pages 1 - 3  
before completing this form.

**Identifying Information**

1. Employee's name (last, first, middle) ANDRUS, CHARLES, H	2. Date of birth (mm/dd/yyyy) 03/28/1953	3. Social Security number 563-94-2723
4. Employing department/agency Department of Veterans Affairs	5. Work location (city, state, ZIP) St. Louis, MO 63106	6. Compensation claim number (if applicable)

**Basic Life Insurance**

7. Do you want to have Basic Life insurance in retirement/compensation if you are eligible?

☒ Yes (If yes, complete item 8.) ☐ No ☐ I received a full Living Benefit. (skip to Item 9)

8. What level of Basic do you want in retirement/compensation? Check only one box. If you received a partial Living Benefit, you must check No Reduction.

☒ 75% Reduction ☐ 50% Reduction ☐ No Reduction

**Option A — Standard Optional Insurance**

9. Do you want to have Option A in retirement/compensation if you are eligible? To continue Option A, you must also continue Basic. (Check "yes" only if you currently have as an employee)

☐ Yes ☐ No ☒ I don't have Option A.

**Option B — Additional Optional Insurance**

10. Do you want to have Option B in retirement/compensation if you are eligible? To continue Option B, you must also continue Basic. (Check "yes" only if you currently have as an employee)

☐ Yes (If yes, complete item 11.) ☐ No ☒ I don't have Option B.

11. How many multiples of Option B do you want to have in retirement/compensation? You can elect up to the number of multiples you are eligible to continue in retirement. Put a number on each line to indicate how many multiples you want for NO REDUCTION and FULL REDUCTION. If the number is "zero", "0" should be written on that line. The total of both No and Full Reduction multiples cannot exceed 5. See the instructions.

\_\_\_\_\_ (number of NO REDUCTION multiples) \_\_\_\_\_ (number of FULL REDUCTION multiples)

**Option C — Family Optional Insurance**

12. Do you want to have Option C in retirement/compensation if you are eligible? To continue Option C, you must also continue Basic. (Check "yes" only if you currently have as an employee.)

☐ Yes (If yes, complete item 13.) ☐ No ☒ I don't have Option C.

13. How many multiples of Option C do you want to have in retirement/compensation? You can elect up to the number of multiples you are eligible to continue in retirement. Put a number on each line to indicate how many multiples you want for NO REDUCTION and FULL REDUCTION. If the number is "zero", "0" should be written on that line. The total of both No and Full Reduction multiples cannot exceed 5. See the instructions.

\_\_\_\_\_ (number of NO REDUCTION multiples) \_\_\_\_\_ (number of FULL REDUCTION multiples)

**Signature**

14. Signature (Do not print.) Only the insured may sign. Signatures by guardians, conservators, or through a power of attorney are not acceptable.

*Charles H. Andrus, M.D., FACS* Date (mm/dd/yyyy) *01/22/2023*



ANDRUS CHARLES H (657)									
station	PayPeriod	PayYear	Health Insurance Emp	Health Insurance VA	Life Insurance Emp	Life Insurance VA Share	Health Insurance Code	FEGLI code	
657	26	2022	0	524.63	0	0	106	C0	
657	01	2023	0	560.52	0	0	106	C0	

ANDRUS CHARLES H (657)									
station	PayPeriod	PayYear	Health Insurance Emp	Health Insurance VA	Life Insurance Emp	Life Insurance VA Share	Health Insurance Code	FEGLI code	
657	26	2021	280.81	517.46	50.56	25.28	106	C0	
657	01	2022	289.61	524.63	51.04	25.52	106	C0	
657	02	2022	289.61	524.63	51.04	25.52	106	C0	
657	03	2022	289.61	524.63	51.04	25.52	106	C0	
657	04	2022	289.61	524.63	51.04	25.52	106	C0	
657	05	2022	289.61	524.63	51.04	25.52	106	C0	
657	06	2022	289.61	524.63	51.04	25.52	106	C0	
657	07	2022	289.61	524.63	51.04	25.52	106	C0	
657	08	2022	289.61	524.63	51.04	25.52	106	C0	
657	09	2022	289.61	524.63	51.04	25.52	106	C0	
657	10	2022	289.61	524.63	51.04	25.52	106	C0	
657	11	2022	289.61	524.63	51.04	25.52	106	C0	
657	12	2022	289.61	524.63	51.04	25.52	106	C0	
657	13	2022	289.61	524.63	51.04	25.52	106	C0	
657	14	2022	289.61	524.63	51.04	25.52	106	C0	
657	15	2022	289.61	524.63	51.04	25.52	106	C0	
657	16	2022	289.61	524.63	51.68	25.84	106	C0	
657	17	2022	289.61	524.63	51.68	25.84	106	C0	
657	18	2022	289.61	524.63	51.68	25.84	106	C0	
657	19	2022	289.61	524.63	51.68	25.84	106	C0	
657	20	2022	289.61	524.63	51.68	25.84	106	C0	
657	21	2022	289.61	524.63	51.68	25.84	106	C0	
657	22	2022	289.61	524.63	51.68	25.84	106	C0	
657	23	2022	0	524.63	0	0	106	C0	
657	24	2022	0	524.63	0	0	106	C0	
657	25	2022	0	524.63	0	0	106	C0	

ANDRUS CHARLES H (657)									
station	PayPeriod	PayYear	Health Insurance Emp	Health Insurance VA	Life Insurance Emp	Life Insurance VA Share	Health Insurance Code	FEGLI code	
657	26	2020	267.15	504.12	47.1	23.55	106	C0	
657	01	2021	280.81	517.46	47.4	23.7	106	C0	
657	02	2021	280.81	517.46	47.4	23.7	106	C0	
657	03	2021	280.81	517.46	47.4	23.7	106	C0	
657	04	2021	280.81	517.46	47.4	23.7	106	C0	
657	05	2021	280.81	517.46	47.4	23.7	106	C0	
657	06	2021	280.81	517.46	47.4	23.7	106	C0	
657	07	2021	280.81	517.46	47.4	23.7	106	C0	
657	08	2021	280.81	517.46	47.4	23.7	106	C0	
657	09	2021	280.81	517.46	47.4	23.7	106	C0	
657	10	2021	280.81	517.46	47.4	23.7	106	C0	
657	11	2021	280.81	517.46	47.4	23.7	106	C0	
657	12	2021	280.81	517.46	47.4	23.7	106	C0	
657	13	2021	280.81	517.46	47.4	23.7	106	C0	
657	14	2021	280.81	517.46	47.4	23.7	106	C0	
657	15	2021	280.81	517.46	47.4	23.7	106	C0	
657	16	2021	280.81	517.46	47.4	23.7	106	C0	
657	17	2021	280.81	517.46	47.4	23.7	106	C0	
657	18	2021	280.81	517.46	47.4	23.7	106	C0	
657	19	2021	280.81	517.46	47.4	23.7	106	C0	
657	20	2021	280.81	517.46	47.4	23.7	106	C0	
657	21	2021	280.81	517.46	50.56	25.28	106	C0	
657	22	2021	280.81	517.46	50.56	25.28	106	C0	
657	23	2021	280.81	517.46	50.56	25.28	106	C0	
657	24	2021	280.81	517.46	50.56	25.28	106	C0	
657	25	2021	280.81	517.46	50.56	25.28	106	C0	



ANDRUS CHARLES H (657)									
station	PayPeriod	PayYear	Health Insurance Emp	Health Insurance VA	Life Insurance Emp	Life Insurance VA Share	Health Insurance Code	FEGLI code	
657	26	2019	256.54	492.27	46.05	23.03	106	C0	
657	01	2020	267.15	504.12	46.65	23.33	106	C0	
657	02	2020	267.15	504.12	46.65	23.33	106	C0	
657	03	2020	267.15	504.12	46.65	23.33	106	C0	
657	04	2020	267.15	504.12	46.65	23.33	106	C0	
657	05	2020	267.15	504.12	46.65	23.33	106	C0	
657	06	2020	267.15	504.12	46.65	23.33	106	C0	
657	07	2020	267.15	504.12	46.65	23.33	106	C0	
657	08	2020	267.15	504.12	46.65	23.33	106	C0	
657	09	2020	267.15	504.12	46.65	23.33	106	C0	
657	10	2020	267.15	504.12	46.65	23.33	106	C0	
657	11	2020	267.15	504.12	46.65	23.33	106	C0	
657	12	2020	267.15	504.12	46.65	23.33	106	C0	
657	13	2020	267.15	504.12	46.65	23.33	106	C0	
657	14	2020	267.15	504.12	46.65	23.33	106	C0	
657	15	2020	267.15	504.12	46.65	23.33	106	C0	
657	16	2020	267.15	504.12	47.1	23.55	106	C0	
657	17	2020	267.15	504.12	47.1	23.55	106	C0	
657	18	2020	267.15	504.12	47.1	23.55	106	C0	
657	19	2020	267.15	504.12	47.1	23.55	106	C0	
657	20	2020	267.15	504.12	47.1	23.55	106	C0	
657	21	2020	267.15	504.12	47.1	23.55	106	C0	
657	22	2020	267.15	504.12	47.1	23.55	106	C0	
657	23	2020	267.15	504.12	47.1	23.55	106	C0	
657	24	2020	267.15	504.12	47.1	23.55	106	C0	
657	25	2020	267.15	504.12	47.1	23.55	106	C0	

ANDRUS CHARLES H (657)									
station	PayPeriod	PayYear	Health Insurance Emp	Health Insurance VA	Life Insurance Emp	Life Insurance VA Share	Health Insurance Code	FEGLI code	
657	26	2018	257.81	491	40.05	20.03	106	C0	
657	01	2019	256.54	492.27	40.05	20.03	106	C0	
657	02	2019	256.54	492.27	40.05	20.03	106	C0	
657	03	2019	256.54	492.27	40.05	20.03	106	C0	
657	04	2019	256.54	492.27	40.05	20.03	106	C0	
657	05	2019	256.54	492.27	40.05	20.03	106	C0	
657	06	2019	256.54	492.27	40.05	20.03	106	C0	
657	07	2019	256.54	492.27	40.05	20.03	106	C0	
657	08	2019	256.54	492.27	40.05	20.03	106	C0	
657	09	2019	256.54	492.27	40.05	20.03	106	C0	
657	10	2019	256.54	492.27	40.05	20.03	106	C0	
657	11	2019	256.54	492.27	40.05	20.03	106	C0	
657	12	2019	256.54	492.27	40.05	20.03	106	C0	
657	13	2019	256.54	492.27	40.05	20.03	106	C0	
657	14	2019	256.54	492.27	40.05	20.03	106	C0	
657	15	2019	256.54	492.27	40.05	20.03	106	C0	
657	16	2019	256.54	492.27	40.05	20.03	106	C0	
657	17	2019	256.54	492.27	169.65	84.83	106	C0	
657	18	2019	256.54	492.27	44.85	22.43	106	C0	
657	19	2019	256.54	492.27	83.7	41.75	106	C0	
657	20	2019	256.54	492.27	46.05	23.03	106	C0	
657	21	2019	256.54	492.27	46.05	23.03	106	C0	
657	22	2019	256.54	492.27	46.05	23.03	106	C0	
657	23	2019	256.54	492.27	46.05	23.03	106	C0	
657	24	2019	256.54	492.27	46.05	23.03	106	C0	
657	25	2019	256.54	492.27	46.05	23.03	106	C0	



ANDRUS CHARLES H (657)									
station	Pay Period	Pay Year	Health Insurance Emp	Health Insurance VA	Life Insurance Emp	Life Insurance VA Share	Health Insurance Code	FEGLI code	
657	26	2017	240.77	475.79	40.05	20.03	106	C0	
657	01	2018	257.81	491	40.05	20.03	106	C0	
657	02	2018	257.81	491	40.05	20.03	106	C0	
657	03	2018	257.81	491	40.05	20.03	106	C0	
657	04	2018	257.81	491	40.05	20.03	106	C0	
657	05	2018	257.81	491	40.05	20.03	106	C0	
657	06	2018	257.81	491	40.05	20.03	106	C0	
657	07	2018	257.81	491	40.05	20.03	106	C0	
657	08	2018	257.81	491	40.05	20.03	106	C0	
657	09	2018	257.81	491	40.05	20.03	106	C0	
657	10	2018	257.81	491	40.05	20.03	106	C0	
657	11	2018	257.81	491	40.05	20.03	106	C0	
657	12	2018	257.81	491	40.05	20.03	106	C0	
657	13	2018	257.81	491	40.05	20.03	106	C0	
657	14	2018	257.81	491	40.05	20.03	106	C0	
657	15	2018	257.81	491	40.05	20.03	106	C0	
657	16	2018	257.81	491	40.05	20.03	106	C0	
657	17	2018	257.81	491	40.05	20.03	106	C0	
657	18	2018	257.81	491	40.05	20.03	106	C0	
657	19	2018	257.81	491	40.05	20.03	106	C0	
657	20	2018	257.81	491	40.05	20.03	106	C0	
657	21	2018	257.81	491	40.05	20.03	106	C0	
657	22	2018	257.81	491	40.05	20.03	106	C0	
657	23	2018	257.81	491	40.05	20.03	106	C0	
657	24	2018	257.81	491	40.05	20.03	106	C0	
657	25	2018	257.81	491	40.05	20.03	106	C0	

ANDRUS CHARLES H (657)									
station	PayPeriod	PayYear	Health Insurance Emp	Health Insurance VA	Life Insurance Emp	Life Insurance VA Share	Health Insurance Code	FEGLI code	
657	26	2016	231.31	461.02	40.05	20.03	106	G0	
657	01	2017	240.77	475.79	40.05	20.03	106	G0	
657	02	2017	240.77	475.79	40.05	20.03	106	G0	
657	03	2017	240.77	475.79	40.05	20.03	106	G0	
657	04	2017	240.77	475.79	40.05	20.03	106	G0	
657	05	2017	240.77	475.79	40.05	20.03	106	G0	
657	06	2017	240.77	475.79	40.05	20.03	106	G0	
657	07	2017	240.77	475.79	40.05	20.03	106	G0	
657	08	2017	240.77	475.79	40.05	20.03	106	G0	
657	09	2017	240.77	475.79	40.05	20.03	106	G0	
657	10	2017	240.77	475.79	40.05	20.03	106	G0	
657	11	2017	240.77	475.79	40.05	20.03	106	G0	
657	12	2017	240.77	475.79	40.05	20.03	106	G0	
657	13	2017	240.77	475.79	40.05	20.03	106	G0	
657	14	2017	240.77	475.79	40.05	20.03	106	G0	
657	15	2017	240.77	475.79	40.05	20.03	106	G0	
657	16	2017	240.77	475.79	40.05	20.03	106	G0	
657	17	2017	240.77	475.79	40.05	20.03	106	G0	
657	18	2017	240.77	475.79	40.05	20.03	106	G0	
657	19	2017	240.77	475.79	40.05	20.03	106	G0	
657	20	2017	240.77	475.79	40.05	20.03	106	G0	
657	21	2017	240.77	475.79	40.05	20.03	106	G0	
657	22	2017	240.77	475.79	40.05	20.03	106	G0	
657	23	2017	240.77	475.79	40.05	20.03	106	G0	
657	24	2017	240.77	475.79	40.05	20.03	106	C0	
657	25	2017	240.77	475.79	40.05	20.03	106	C0	

ANDRUS CHARLES H (657)									
station	PayPeriod	PayYear	Health Insurance Emp	Health Insurance VA	Life Insurance Emp	Life Insurance VA Share	Health Insurance Code	FEGLI code	
657	16	2016	0	0	40.05	20.03	002	C0	
657	17	2016	0	0	40.05	20.03	002	C0	
657	18	2016	231.31	461.02	40.05	20.03	106	G0	
657	19	2016	231.31	461.02	40.05	20.03	106	G0	
657	20	2016	231.31	461.02	40.05	20.03	106	G0	
657	21	2016	231.31	461.02	40.05	20.03	106	G0	
657	22	2016	231.31	461.02	40.05	20.03	106	G0	
657	23	2016	231.31	461.02	40.05	20.03	106	G0	
657	24	2016	231.31	461.02	40.05	20.03	106	G0	
657	25	2016	231.31	461.02	40.05	20.03	106	G0	



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314 289 7034

08/31/2016 14:58

#341 P.004/007

From:VA

10 00431352



# Life Insurance Election

## Federal Employees' Group Life Insurance Program

See Privacy Act Statement on back of Part 3

Form Approved  
OMB No. 3206-0230

### 1 General Instructions

By law, unless you waive all coverage or are ineligible, you are automatically covered for Basic life insurance as an employee. When you first become eligible for FEGLI, you may (1) do nothing and have Basic automatically, (2) elect Basic and any or all of the options, or (3) waive all life insurance coverage. If you are changing a previous election, see the back of Part 3 - Employee Copy.

- Read the back of Part 3 - Employee Copy carefully.
- Assignees completing this form should read Items 5 and 6 on the back of Part 3.
- Give all parts of your completed form to your employing office. Your employing office will complete Section 6 of this form (or its electronic equivalent) and return your copy to you.

**\*This election supersedes all previous elections.\***

### 2

Fill in identifying information concerning the employee.

Name (last, first, middle) <b>Andrus, Charles Hiram</b>	Date of birth (mm/dd/yyyy) <b>03/28/1953</b>	Social Security Number <b>563-94-2723</b>
Employing department or agency <b>VA ST. LOUIS HEALTH CARE SYSTEM</b>	OWCP claim number, if applicable	Location of department or agency where you work (city, state, ZIP code) <b>ST. LOUIS, MO 63125</b>
		Daytime telephone number (including area code) <b>314-894-6620</b>

### 3

To elect or retain Basic, sign and date below. If you do not sign for Basic, you (or your assignee) may not elect or retain any form of optional insurance. If you do not want any insurance at all, skip to Section 5.

<input checked="" type="checkbox"/> <b>Basic</b>	I want Basic. I authorize deductions to pay my share of the cost (Basic may be provided without cost to U.S. Postal Service employees).	SIGNATURE (Do not print. Only you or your assignee may sign. Signatures by guardians, conservators or through a power of attorney are not valid.) <b>Charles H Andrus MD</b>	Date (mm/dd/yyyy) <b>08/25/2016</b>
--	---	---	--

### 4

If you signed for Basic in item 3 above, you may elect or retain any or all of the following options (UNLESS you have previously waived any or all of these options, in which case you may elect only those options which you are eligible to elect as outlined in the FEGLI Program Booklet). Sign the box(es) below for any option(s) you are eligible for and wish to elect or retain. If you do not sign for an option, you have waived it and your future opportunities to enroll in it are strictly limited.

You will not be covered for any option(s) for which you do not sign below, regardless of whether you previously elected the option(s).

Option A - Standard	Option B - Additional	Option C - Family												
I want Option A. I authorize deductions to pay the full cost.	I want Option B in the multiple of my annual basic pay I indicate below. I authorize deductions to pay the full cost.	I want Option C in the multiple I indicate below. I understand that each multiple is worth \$5,000 upon the death of my spouse, and \$2,500 upon the death of an eligible child. I authorize deductions to pay the full cost.												
	<table><tr><td><input checked="" type="checkbox"/> 1 times my pay</td><td><input type="checkbox"/> 3 times my pay</td></tr><tr><td><input type="checkbox"/> 2 times my pay</td><td><input type="checkbox"/> 4 times my pay</td></tr><tr><td></td><td><input type="checkbox"/> 5 times my pay</td></tr></table>	<input checked="" type="checkbox"/> 1 times my pay	<input type="checkbox"/> 3 times my pay	<input type="checkbox"/> 2 times my pay	<input type="checkbox"/> 4 times my pay		<input type="checkbox"/> 5 times my pay	<table><tr><td><input type="checkbox"/> 1 multiple</td><td><input type="checkbox"/> 3 multiples</td></tr><tr><td><input type="checkbox"/> 2 multiples</td><td><input type="checkbox"/> 4 multiples</td></tr><tr><td></td><td><input type="checkbox"/> 5 multiples</td></tr></table>	<input type="checkbox"/> 1 multiple	<input type="checkbox"/> 3 multiples	<input type="checkbox"/> 2 multiples	<input type="checkbox"/> 4 multiples		<input type="checkbox"/> 5 multiples
<input checked="" type="checkbox"/> 1 times my pay	<input type="checkbox"/> 3 times my pay													
<input type="checkbox"/> 2 times my pay	<input type="checkbox"/> 4 times my pay													
	<input type="checkbox"/> 5 times my pay													
<input type="checkbox"/> 1 multiple	<input type="checkbox"/> 3 multiples													
<input type="checkbox"/> 2 multiples	<input type="checkbox"/> 4 multiples													
	<input type="checkbox"/> 5 multiples													
SIGNATURE (Do not print. Only you or your assignee may sign. Signatures by guardians, conservators or through a power of attorney are not valid.) <b>→ Charles H Andrus MD</b>	SIGNATURE (Do not print. Only you or your assignee may sign. Signatures by guardians, conservators or through a power of attorney are not valid.) <b>→ Charles H Andrus MD</b>	SIGNATURE (Do not print. Only you or your assignee may sign. Signatures by guardians, conservators or through a power of attorney are not valid.) <b>→</b>												
Date (mm/dd/yyyy) <b>08/31/2016</b>	Date (mm/dd/yyyy) <b>08/31/2016</b>	Date (mm/dd/yyyy)												

### 5

If you want NO life insurance coverage, sign and date below.

<input checked="" type="checkbox"/> <b>Waiver of all life insurance coverage</b>	I want NO life insurance coverage. I understand that any life insurance I have will stop at the end of the last day of the pay period in which my employing office receives this waiver. Further, I cannot get Basic life insurance unless (1) I wait at least 1 year after I sign this form and submit satisfactory medical information, or (2) I experience a life event, or (3) I have a break in Federal service of at least 180 days, or (4) I participate in an open season, which is held infrequently. I understand that I cannot get any optional insurance unless I first have Basic. I understand that my decision to waive life insurance coverage now may affect my eligibility for coverage as a retiree.	SIGNATURE (Do not print. Only you or your assignee may sign. Signatures by guardians, conservators or through a power of attorney are not valid.) <b>→</b>	Date (mm/dd/yyyy)
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### 6

Agency Remarks:  
Use

Name and address of employing office <b>VA ST. LOUIS HCS 1 Jefferson Barracks Dr St Louis MO 63125</b>	Date received in employing office (mm/dd/yyyy) <b>09/01/2016</b> <i>I followed the instructions on the back of Part 1.</i>	Effective date of coverage (mm/dd/yyyy) <b>09/04/2016</b>	If new/newly eligible employee, enter "0" for event. Number of event permitting change (See back of Part 2) <b>0</b>
Signature of authorized agency official <b>[Signature]</b>			

This employee's copy of this form, when completed by the employing office, together with the FEGLI Program Booklet (FE 76-23 or FE 76-20 for U.S. Postal Service employees) constitute the employee's Certificate (proof) of insurance.

PART 1 - File in Official Personnel Folder



Standard Form 50  
Rev. 7/91  
U.S. Office of Personnel Management  
FPM Supp. 296-33, Subch. 4

## NOTIFICATION OF PERSONNEL ACTION

1. Name (Last, First, Middle) <b>ANDRUS,CHARLES HIRAM</b>				2. Social Security Number <b>563-94-2723</b>		3. Date of Birth <b>03/28/1953</b>		4. Effective Date <b>08/07/2016</b>							
<b>FIRST ACTION</b>					<b>SECOND ACTION</b>										
5-A. Code <b>170</b>		5-B. Nature of Action <b>EXC APPT</b>			6-A. Code		6-B. Nature of Action								
5-C. Code <b>V8V</b>		5-D. Legal Authority <b>38 USC 7401(1)</b>			6-C. Code		6-D. Legal Authority								
5-E. Code <b>ZEC</b>		5-F. Legal Authority <b>PUBLIC LAW 113-146 DATED AUGUST 7,2014</b>			6-E. Code		6-F. Legal Authority								
7. FROM: Position Title and Number					15. TO: Position Title and Number <b>PHYSICIAN (REGULAR FT)</b> PD: 000000 POSITION: 91186576										
8. Pay Plan	9. Occ. Code	10. Grade or Level	11. Step or Rate	12. Total Salary	13. Pay Basis	16. Pay Plan	17. Occ. Code	18. Grade or Level	19. Step or Rate	20. Total Salary/Award	21. Pay Basis				
						<b>VM</b>	<b>0602</b>	<b>PHYS</b>	<b>07</b>	<b>\$265,000.00</b>	<b>PA</b>				
12A. Basic Pay		12B. Locality Adj.		12C. Adj. Basic Pay		12D. Other Pay		20A. Basic Pay		20B. Locality Adj.		20C. Adj. Basic Pay		20D. Other Pay	
								<b>\$121,147.00</b>		<b>\$143,853.00</b>		<b>\$265,000.00</b>		<b>\$0</b>	
14. Name and Location of Position's Organization					22. Name and Location of Position's Organization <b>VETERANS HEALTH ADMINISTRATION</b> <b>SURGERY SERVICE</b> <b>ST LOUIS MO USA</b>										
<b>EMPLOYEE DATA</b>															
23. Veterans Preference <b>1</b> 1 - None 3 - 10-Point/Disability 5 - 10-Point/Other 2 - 5-Point 4 - 10-Point/Compensable 6 - 10-Point/Compensable/30%					24. Tenure <b>1</b> 0 - None 2 - Conditional 1 - Permanent 3 - Indefinite		25. Agency Use		26. Veterans Preference for RIF <b>YES</b> <b>X</b> <b>NO</b>						
27. FEGLI <b>C0</b> <b>BASIC ONLY</b>					28. Annuitant Indicator <b>9</b> <b>NOT APPLICABLE</b>			29. Pay Rate Determinant <b>0</b> <b>REGULAR RATE</b>							
30. Retirement Plan <b>K</b> <b>FERS AND FICA</b>			31. Service Comp. Date (Leave) <b>08/07/2016</b>		32. Work Schedule <b>F</b> <b>FULL TIME</b>			33. Part-Time Hours Per Biweekly Pay Period							
<b>POSITION DATA</b>															
34. Position Occupied <b>2</b> 1 - Competitive Service 3 - SES General 2 - Excepted Service 4 - SES Career Reserved				35. FLSA Category <b>E</b> E - Exempt N - Nonexempt		36. Appropriation Code <b>8202-2194</b>			37. Bargaining Unit Status <b>1276</b>						
38. Duty Station Code <b>29-7080-510</b>				39. Duty Station (City - County - State or Overseas Location) <b>ST LOUIS MO</b>											
40. Agency Data <b>657</b>		41.		42.		43.		44.							
45. Remarks APPOINTED UNDER THE SPECIAL HIRING AUTHORITY CONTAINED IN 38 U.S.C 7412(B). THE FEDERAL REGISTER NOTICE IDENTIFYING THIS POSITION AS A SHORTAGE CATEGORY FOR THE FISCAL YEAR IN WHICH APPOINTED IS ON FILE COMPENSATION PANEL APPROVED ON 7/22/2016 APPOINTMENT AFFIDAVIT EXECUTED 08/08/2016 BOARD ACTION APPROVED 07/07/2016 CONTINUED EMPLOYMENT IN THIS POSITION IS CONDITIONED UPON FAVORABLE ADJUDICATION OF APPLICABLE BACKGROUND INVESTIGATION OR NATIONAL AGENCY CHECK WITH WRITTEN INQUIRIES (NACI). FROZEN SERVICE: NONE CREDITABLE MILITARY SERVICE: NONE PREVIOUS RETIREMENT COVERAGE: FERS EMPLOYEE IS AUTOMATICALLY COVERED UNDER FERS															
46. Employing Department or Agency <b>DEPARTMENT OF VETERANS AFFAIRS</b>						50. Signature/Authentication and Title of Approving Official ELECTRONICALLY SIGNED BY: <b>JILL VAUGHN</b> <b>HUMAN RESOURCES OFFICER</b>									
47. Agency Code <b>VATA</b>		48. Personnel Office ID <b>1783</b>		49. Approval Date <b>08/07/2016</b>											



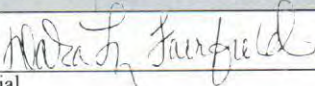


## Notice of Conversion Privilege Federal Employees' Group Life Insurance Program

### Part A - Instructions to Employing Agency

Complete Part A of this form whenever an employee's life insurance coverage terminates due to separation, resignation, retirement, death or end of 12 months in non-pay status. On the date insurance terminates (except by waiver), give this notice to every employee and/or the assignee(s), if applicable, and to the family of each deceased employee who had the Option

C-Family coverage. Also, upon request, give this notice to the family of an eligible employee who does not convert his or her Option C-Family insurance. If this notice is prepared for a retiring employee, forward Part 2 (duplicate) to OPM with the employee's retirement papers. Otherwise, place Part 2 (duplicate) in the employee's Official Personnel Folder.

1. Name of employee ANDRUS, CHARLES, H	2. Date of birth (mo., day, yr.) 03/28/1953	3. Date insurance terminated 11/3/2022
4. Was employee insured for Option C-Family insurance on date in item 3?	Yes	<input checked="" type="checkbox"/> No
<b>Agency Certification</b> <i>I certify that the above information has been obtained from, and correctly reflects, official personnel records.</i>		
5. Signature of authorized agency official 	6. Name and mailing address of agency Department of Veterans Affairs 120 SE 6th Ave. Ste. 102 Topeka, KS 66603	
7. Typed name of authorized agency official Dara M. Fairfield		
8. Title Human Resources Specialist		
9. Telephone number (866) 330-7366	10. Date of this notice (mo., day, yr.) 1/29/2023	

### Part B - Conversion Information for Employees, Assignees, and Family Members Who are Losing FEGLI Coverage

If you are eligible and you will be carrying all of your Federal Employees' Group Life Insurance (FEGLI) coverage into retirement, do not apply for conversion. Employees (and assignees, if applicable) and their family members who are losing FEGLI coverage, however, may be eligible and wish to convert some or all of their coverage to an individual direct-pay policy.

**Employees** - If you have not assigned your FEGLI coverage, you are entitled to convert to an individual direct-pay policy unless, within 3 calendar days after the date your insurance terminates, you return to a Government position that qualifies you to reacquire FEGLI coverage. You may purchase an individual policy in an amount equal to or less than your Basic life insurance plus any optional coverage you may have.

**Assignees** - You are entitled to convert your share of the insured's FEGLI coverage to an individual direct-pay policy unless, within 3 calendar days after the date the insured's insurance terminates, he/she returns to a Government position that qualifies him/her to reacquire FEGLI coverage. If that is the case, his/her previous assignment is still valid. You may purchase an individual policy in an amount equal to or less than the amount of insurance which the insured assigned to you.

**Family members** - If, upon termination of the employee's FEGLI coverage, he/she does not convert Option C-Family coverage (if any), you, as an eligible family member, may do so. Spouses may convert up to \$5,000, and eligible children up to \$2,500 each. Eligible family members are the employee's spouse and unmarried dependent children under age 22 (including adopted children, stepchildren who lived with the employee in a regular parent-child relationship, and recognized natural children) and unmarried dependent children over age 22 who are incapable of self-support because of a mental or physical disability that existed before they reached age 22.

**Your time to convert is limited** - You must mail your request for information regarding conversion within 31 days of the date in item 3 of Part A above, or within 31 days of the date you receive this notice, whichever gives you more time. If you fail to request conversion information within the 31-day time limit due to a cause beyond your control, you may be allowed to convert your life insurance within six months after the date in item 3, provided you attach a full explanation of what prevented you from making a timely request. If approved, the effective date of the conversion policy will be retroactive to the day following the day group coverage ended.

**Note:** Under certain circumstances, life insurance is payable if death occurs within 31 days after the group life insurance terminates, regardless of whether conversion has been requested. However, extension of the conversion privilege beyond 31 days does not extend coverage under any circumstances. If death occurs within the 31-day period, further information concerning possible benefits may be obtained from the agency named in item 6 above.

#### General information about conversion

- If you have assigned your FEGLI coverage, you can **only** convert your Option C coverage (if any). Your assignee(s) retain(s) the right to convert your other coverage(s).
- No medical examination is required.
- You or the assignee(s), if applicable, must pay the premium applicable to the individual policy.
- The government will not pay any part of the individual policy premium.
- The individual policy will be issued by an insurance company you select from the list of eligible companies you will receive if you apply for conversion.
- The individual policy may be an ordinary life policy or a variation of ordinary life (see Part D). It must be a type of insurance customarily issued by the insurance company you select. However, it cannot be term insurance or universal life insurance or any other form of life insurance that has an indeterminate premium. It cannot have disability or accidental death and dismemberment benefits.

#### How to convert

1. Complete the appropriate eligibility statement on the reverse side of this form and mail it to the Office of Federal Employees' Group Life Insurance (OFEGLI), 200 Park Avenue, New York, NY 10166-0188.
2. If you have an SF 2821, Agency Certification of Insurance Status, attach the original (Part 1) to this form when you mail it to OFEGLI. Note: Retiring employees (and assignees of those employees) who are continuing Basic Life insurance but converting one or more of the options should submit their duplicate (Part 2) of the SF 2821 with this form to OFEGLI. The original (Part 1) of the SF 2821 should be submitted with the retirement application. OFEGLI will mail you detailed information on how to apply for conversion, together with a list of eligible insurance companies. You have 31 days (from the date in item 3 of Part A above, or the date you receive this notice, whichever gives you more time) to request conversion information from OFEGLI.
3. In the event you do not have an SF 2821, you should request a completed form from the employing agency before the expiration of your 31 day time limit and forward it to OFEGLI at the address given in item 1 above.  
**However, don't delay sending the SF 2819 requesting conversion information to OFEGLI -- send it anyway while you await the SF 2821.**
4. If you are using this form to convert some of your life insurance coverage, but not Option C, have your employing office prepare another SF 2819 for your family members.
5. Family members may apply for conversion by sending a completed SF 2819 (this form) to OFEGLI, 200 Park Avenue, New York, NY 10166-0188. (Note: Family members do not need an SF 2821.)

### Part 2 - Forward with Retirement Papers/File in OPF



RECEIVED 04/28/2011 05:22

From:VA

314 289 7034

08/31/2016 14:59

#341 P.006/007



**Designation of Beneficiary**  
**Federal Employees' Group Life Insurance (FEGLI) Program**  
(DO NOT erase or cross-out. Use a new form.)

Form Approved  
OMB No. 3208-0136

**Important:**  
Read instructions on the  
Back of Part 2 before completing this form.

**A. Information About the Insured (not the Assignee, if there is one) (type or print)**

Name of Insured (Last, first, middle) <u>Andrus, Charles Hiram</u>	Date of birth of Insured (mm/dd/yyyy) <u>03/28/1953</u>	Social Security Number of Insured <u>563-94-2723</u>
The Insured is: Place an "X" in the appropriate box <input checked="" type="checkbox"/> an employee <input type="checkbox"/> a retiree <input type="checkbox"/> a compensationner		
If the Insured is retired or receiving Federal Employees' Compensation, give CSA, CSI, or OWCP claim number		

Department or agency where the Insured works (If retired, last department or agency where the Insured worked):

Department or agency

VHASTLHCS

Bureau or division

JC

Location (city, state, and ZIP code)

ST. LOUIS, MO 63125

**B. Information About the Beneficiary or Beneficiaries (See Back of Part 1 for examples) (type or print)**

First name, middle initial, and last name of each beneficiary	Social Security Number	Address (including ZIP code)	Relationship	Percent or fraction designated
<u>Pamela B Andrus</u>	<u>522-04-5324</u>	<u>150 Emerald Green Ct</u> <u>St. Louis, MO 63141</u>	<u>wife</u>	<u>100%</u>

Total (Must equal 100% or 1.0) (Do not use dollar amounts)

(Do not put a Total if you designated types of insurance. See example 4 on Back of Part 1.)

100%**C. Statement of Insured or Assignee (type or print)**

Your name and address (including ZIP code) <u>Charles Andrus MD</u> <u>150 Emerald Green Ct</u> <u>St Louis MO 63141</u>	Please check one: I am <input checked="" type="checkbox"/> the Insured <input type="checkbox"/> an Assignee	Please check all three: <input checked="" type="checkbox"/> I have not assigned the insurance. <input checked="" type="checkbox"/> Two people who witnessed my signature signed below. <input checked="" type="checkbox"/> I did not name either witness as a beneficiary.
	See Back of Part 2 for definitions	

I understand that if there is a valid assignment on file, only the assignee has the right to designate a beneficiary. If a valid assignment is not on file, but there is a valid court order on file with the agency or the U.S. Office of Personnel Management, as appropriate, any designation I complete for the same benefits is not valid.

I understand that if this Designation is valid, it will stay in effect unless it is canceled. (See "When Is A Designation Canceled?" on the Back of Part 2.)

I understand that if this Designation is invalid for any reason, the Office of Federal Employees' Group Life Insurance will pay benefits according to the next most recent valid designation. If there isn't one, it will pay according to the order listed on the Back of Part 2.

I am canceling any and all previous Designations of Beneficiary under the Federal Employees' Group Life Insurance Program and am now designating the beneficiary(ies) named above.

Signature of Insured/Assignee (Only the Insured/Assignee may sign. Signatures by guardians, conservators or through a power of attorney are not acceptable.) This form is not valid unless the Insured/Assignee signs in this box.

Charles H. Andrus MD

Date (mm/dd/yyyy)

08/25/2016**D. Witnesses To Signature (A witness is not eligible to receive a payment as a beneficiary.)**

Signature of witness <u>Madeline</u>	Address (including ZIP code) <u>1957 Hawksbill Dr Belleville, IL 62223</u>
Signature of witness <u>Requelyn Crawford</u>	Address (including ZIP code) <u>8921 Hillview Ave 63136</u>

**E. For Agency Use Only (or OPM, as appropriate)**

Receiving agency <u>ST. LOUIS VA HCS</u>	Date of receipt (mm/dd/yyyy) <u>09/01/2016</u>	Signature of authorized official <u>HBK</u>	Title <u>HR Specialist</u>
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Part 1 - Original





## Application for Immediate Retirement Federal Employees Retirement System

See Privacy Act  
Information on  
Instruction Sheet

### Section A - Identifying Information

1. Name (last, first, middle) ANDRUS, CHARLES, H		2. List all other names you have used	
3. Address (number, street, city, state, ZIP code) 150 Emerald Green Ct St. Louis, MO 63141-7541		4a. Daytime telephone # after retirement (including area code) 314-455-9482 or 314-809-9634	4b. Best time to reach you Any Time - Day or Night
		4c. Home email address candrus600@aol.com	4d. FAX Number 314-455-9482
		5. Date of birth (mm/dd/yyyy) 03/28/1953	6. Social Security Number 563-94-2723
7. Are you a citizen of the United States of America? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No		8. Is this an application for disability retirement? Yes (Ask your employing office about other documents you must submit) <input checked="" type="checkbox"/> No	

### Section B - Federal Service

1. Department or agency from which you are retiring (include bureau or division, address and ZIP code) Department of Veterans Affairs 915 North Grand Blvd. St. Louis, MO 63106		2. Date of final separation (mm/dd/yyyy) 11/3/2022
		3. Title of position from which you are retiring Physician
		3a. Your pay plan and occupational series VM 0602
4. Have you performed active honorable service in the Armed Forces or other uniformed services of the United States (see instructions for definitions)? <input type="checkbox"/> Yes (Complete Schedule A and attach it to this form) <input checked="" type="checkbox"/> No		
5. Are you receiving or have you applied for military retired pay? (Note: If you later become entitled to military retired pay you must notify OPM.) <input type="checkbox"/> Yes (Complete Schedule B and attach it to this form) <input checked="" type="checkbox"/> No		

### Section C - Marital Information (All applicants must complete questions 1 and 2 below.)

1. Are you married now? (A marriage exists until ended by death, divorce, or annulment.) <input checked="" type="checkbox"/> Yes (Complete items 1a - 1f and attach a copy of your marriage certificate) <input type="checkbox"/> No (Go to item 2)		
1a. Spouse's name (last, first, middle) Andrus, Pamela, Bergkamp	1b. Spouse's date of birth (mm/dd/yyyy) 04/30/1959	1c. Spouse's Social Security Number 522-04-5324
1d. Place of marriage (city, state) Denver, CO	1e. Date of marriage (mm/dd/yyyy) 7/27/1985	1f. Marriage performed by: <input checked="" type="checkbox"/> Clergyman or Justice of Peace Other (explain):
2. Do you have a living former spouse(s) to whom a court order gives a survivor annuity or a portion of your retirement benefits based on your Federal employment? <input type="checkbox"/> Yes (Attach a certified copy of the court order[s] and any amendments.) <input checked="" type="checkbox"/> No		

### Section D - Annuity Election

Make your election by initialing the box beside the type of annuity you want to receive and give any other information requested. Read the pamphlet SF 3113, *Applying for Immediate Retirement under FERS* and the explanations below and consider your election carefully. No change will be permitted after your annuity is granted except as explained in the pamphlet. If you are married at retirement, the law provides an annuity with full survivor benefits for your spouse unless your spouse consents to your election not to provide maximum survivor benefits.

Your election to provide a survivor annuity for a current spouse terminates upon the death of that spouse or if the marriage ends due to divorce or annulment. You are required to make a new election (reelect) within 2 years of the terminating event if you wish to reelect a survivor annuity for a former spouse or within 2 years of a post-retirement marriage to elect a survivor annuity for a spouse acquired after retirement. Continuing a survivor reduction by itself, is not effective to reelect a survivor annuity for a spouse married after retirement or for a former spouse.

If you want to elect a partial survivor annuity for your current spouse and a survivor benefit for a former spouse, you should complete options 2 and 5 below. The total of the survivor annuities elected cannot exceed 50 percent. An election of an insurable interest survivor in option 4 is not included when determining the 50 percent maximum.

1. <b>Initials</b> CHA	I choose a reduced annuity with maximum survivor annuity for my spouse named in Section C. If you are married at retirement, you will receive this type of annuity unless your spouse consents to your election not to provide maximum survivor benefits. If you receive this annuity, your annuity will be reduced by 10%. Your spouse's annuity upon your death will be 50% of your unreduced earned annuity.
2. <b>Initials</b>	I choose a reduced annuity with a partial survivor annuity for my spouse named in Section C. If you choose this option, your annuity will be reduced by 5%. Upon your death, your spouse's annuity will be 25% of your unreduced earned annuity. You must have your spouse's consent to choose this option. Complete form SF 3107-2, <i>Spouse's Consent to Survivor Election</i> , and attach it to your application.
3. <b>Initials</b>	I choose an annuity payable only during my lifetime. If you are married at retirement, you cannot choose this type of annuity without your spouse's consent. No survivor annuity will be paid to your spouse after your death if he or she consents to this election and any health benefits will cease. In addition, your spouse will not be eligible to enroll in the Federal Long Term Care Insurance Program, if he/she is not enrolled at the time of your death. If you are married and elect this, complete form SF 3107-2, <i>Spouse's Consent to Survivor Election</i> , and attach it to your application.



4. **Initials** *I choose a reduced annuity with survivor annuity for the person named below who has an insurable interest in me. You must be healthy and willing to provide medical evidence if you choose this type of annuity. (Disability annuitants are not eligible to choose this type of annuity.) If you are married and elect this option for your spouse, complete SF 3107-2, Spouse's Consent to Survivor Election and attach it to your application.*

Name of person with insurable interest	Relationship to you	Date of birth (mm/dd/yyyy)	Social Security Number
--	---------------------	----------------------------	------------------------

5. **Initials** *I choose a reduced annuity with survivor annuity for my former spouse(s) as follows: You must attach: (1) Copies of divorce decrees for all former spouses for whom you elect to provide a survivor annuity. (2) If you are married, attach a completed SF 3107-2, Spouse's Consent to Survivor Election. You cannot choose this option and provide a maximum survivor annuity for your spouse (Box 1). Your election to provide a survivor annuity for a former spouse terminates upon the death of that spouse or the remarriage of your former spouse before age 55.*

Name and address of former spouse	Date of marriage (mm/dd/yyyy)	Date of divorce (mm/dd/yyyy)	Survivor annuity equal to _____ % of my annuity
	Date of birth (mm/dd/yyyy)	Social Security Number	
Name and address of former spouse	Date of marriage (mm/dd/yyyy)	Date of divorce (mm/dd/yyyy)	Survivor annuity equal to _____ % of my annuity
	Date of birth (mm/dd/yyyy)	Social Security Number	

Total (either 25% or 50% of your unreduced annuity) ☒ 25% ☐ 50%

### Section E - Insurance Information

See the pamphlet SF 3113, *Applying for Immediate Retirement Under the Federal Employees Retirement System*, for information.

1a. Are you eligible to continue Federal Employees Health Benefits coverage as a retiree?  
☒ Yes ☐ No

1b. Is there a court order or administrative order currently in effect that requires you to provide health benefits coverage for your child(ren)?  
☐ Yes (Attach a copy of the court/administrative order) ☒ No

2. Are you eligible to continue Federal Employee's Group Life Insurance coverage as a retiree?  
☒ Yes ☐ No

3. Are you enrolled in the Federal Dental and Vision Insurance Program (FEDVIP)?  
☒ Yes ☐ No *Your coverage will automatically continue into retirement as long as you continue to pay applicable premiums. Until work on your annuity is completed, you may receive bills from BENEFEDS. You must pay these bills in order to keep your FEDVIP coverage. After work on your annuity is completed, BENEFEDS will automatically begin deducting from your annuity to pay future premiums. If you have questions, please contact BENEFEDS at 1-877-888-3337.*

☐ No *If you retire on an immediate annuity, you can enroll in FEDVIP during any Federal Benefits Open Season.*

4. Are you currently enrolled in the Federal Long Term Care Insurance Program (FLTCIP)?  
☐ Yes ☒ No *You will automatically continue your coverage into retirement, as long as you continue to pay applicable premiums. If you are currently paying FLTCIP premiums by agency payroll deduction, you must arrange to pay premiums another way, either by deductions from your annuity, through automatic bank debit or direct bill. Please call LTC Partners at 1-800-LTC-FEDS (1-800-582-3337) to make these arrangements.*

### Section F - Other Claim Information

1. Have you applied for, are you receiving, or have you ever received workers' compensation from the Department of Labor because of a job-related illness or injury?  
☐ Yes (Complete Schedule C and attach it to this form) ☒ No

2. Have you previously filed any application under the Civil Service Retirement System or Federal Employees Retirement System (for retirement, refund, deposit or redeposit, or voluntary contributions)?  
☒ Yes (Complete items 2a and 2b below.) ☐ No

2a. Type of application  
☐ Retirement ☐ Refund ☐ Return of excess deductions ☒ Deposit or redeposit ☐ Voluntary contributions

2b. Claim number(s)  
CSD 7072932

### Section G (Optional) - Information About Your Unmarried Dependent Children

1. Dependent child's name (first, middle, last)	2. Date of birth (mm/dd/yyyy)	3. Disabled (✓)	1. Dependent child's name (first, middle, last)	2. Date of birth (mm/dd/yyyy)	3. Disabled (✓)

3107-107



## Section H - Payment Instructions

1. Federal benefits payments will be made electronically by Direct Deposit into a savings or checking account or by a Direct Express debit card provided by the Department of the Treasury. See the instructions for Section H of this application and SF 3113 (Applying for Immediate Retirement Under the Federal Employees Retirement System) for additional information. This does not apply to you if your permanent payment address is outside the United States in a country not accessible via direct deposit.

Please select one of the following:

- ☒ Please send my annuity payments directly to my checking or savings account. (Go to item 2)
- ☐ Please send my annuity payments to my Direct Express debit card. (Go to item 3a)
- ☐ My permanent payment address is outside the United States in a country not accessible via Direct Deposit/Direct Express. (Go to item 3a)

2a. Financial Institution Routing Number 081000210		<i>You may obtain this number by calling your bank, credit union, or savings institution. This number is very important. We cannot pay by direct deposit without it.</i>	
2b. Checking or Savings Account Number 152305254806	2c. What kind of account is this? <input checked="" type="checkbox"/> Checking <input type="checkbox"/> Savings	2d. Telephone number of your Financial Institution (including area code) 314-387-2301	
2e. Name and address of Financial Institution US BANK  11532 Page Service Dr.  St. Louis, MO 63146		<b>Special Note:</b> If you prefer, you may attach a cancelled personal check that shows the information requested above, instead of filling in the requested financial institution information. If you attach your personal check, it is especially important that you contact your bank, credit union, or savings institution to confirm that the information on the check is the correct information for direct deposit. (Some institutions, especially credit unions, use different routing numbers on checks.) We can then use this information to start paying you by direct deposit.	
3a. Do you want Federal income tax withheld from your annuity payments?  <input checked="" type="checkbox"/> Yes (Go to item 3b) <input type="checkbox"/> No (Go to Section I)		3b. Do you want to have Federal Income Tax withheld at the rate currently being withheld from your salary?  <input type="checkbox"/> Yes (Attach copy of W-4 form on file with your employing agency.) <input checked="" type="checkbox"/> No (Attach new W-4 form, otherwise withholding will be at rate for married with 3 exemptions.)	

## Section I - Applicant's Certification

### Warning

Any intentionally false statement in this application or willful misrepresentation relative thereto is a violation of the law punishable by a fine of not more than \$10,000 or imprisonment of not more than 5 years, or both. (18 U.S.C. 1001)

I hereby certify that all statements made in this application are true to the best of my knowledge and belief.

Signature (Do not print)

Charles H. Andrus, MD, FACS

Date (mm/dd/yyyy)

01/22/2023

### Applicant's Checklist

This checklist is provided to help you be certain you have attached all necessary documentation and to help your employing office be certain it forwards all of your retirement documentation to the Office of Personnel Management.

- |  | Yes | No | Not Applicable |
|--|-----|----|----------------|
| 1. <b>Military Service</b> - If you answered "yes" to Section B, Item 4, did you attach Schedule A?  |     |    | X              |
| 2. <b>Military Service</b> - If you completed Schedule A, did you attach a copy of your discharge certificate or other certificate of active military service?   |     |    | X              |
| 3. <b>Military Retired Pay</b> - If you answered "yes" to Section B, Item 5, did you attach Schedule B?  |     |    | X              |
| 4. <b>Military Retired Pay</b> - If you completed Schedule B and answered "yes" to Item b or c, did you attach a copy of the notice of award or other documentation of the type of military retired pay you are receiving?                                     |     |    | X              |
| 5. <b>Military Retired Pay</b> - If you completed Schedule B and answered "yes" to item d, did you attach a copy of your request for waiver and a copy of the military finance office's acknowledgment or approval of your request for waiver (if applicable)? |     |    | X              |
| 6. <b>Survivor Election</b> - If you are married and did not initial box 1 of Section D, did you attach SF 3107-2, Spouse's Consent to Survivor Election?  |     |    | X              |
| 7. <b>Life Insurance</b> - If you answered "yes" to Section E, item 2, did you attach SF 2818, Continuation of Life Insurance Coverage As an Annuitant or Compensation?  | X   |    |                |
| 8. <b>OWCP</b> - If you answered "yes" to Section F, item 1, did you attach Schedule C?  |     |    | X              |
| 9. <b>Tax</b> - If you want to elect a Federal Income Tax withholding rate, did you attach a W-4 form?   | X   |    |                |
| 10. <b>Court or Administrative Order(s)</b> - If you answered "yes" to Section C, item 2 and/or "yes" to Section E, Item 1b, did you attach a copy of the order(s)?  |     |    | X              |



## FERS Benefit Estimate Report CHARLES H ANDRUS

### Optional Retirement Annuity

Unreduced Monthly Annuity	\$6,337.93
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#### Reductions

Early Retirement Age	\$0.00
Unpaid CSRS Deposit	\$0.00
Survivor Benefit	\$633.79
Unpaid CSRS Redeposit	\$0.00
Alternative Annuity	\$0.00

Total Reductions	\$633.79
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GROSS MONTHLY ANNUITY	\$5,704.00
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#### Deductions

Health Insurance Premium	\$690.84
Life Insurance Premium	\$0.00
Dental Insurance Premium	\$0.00
Vision Insurance Premium	\$0.00
Federal Tax Withholding	\$500.00

Total Deductions	\$1,190.84
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NET MONTHLY ANNUITY	\$4,513.16
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FERS Annuity Supplement:	\$0.00
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Monthly Survivor Annuity Elected	\$3,168.00
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### Service Credits

	Yrs	Mos	Days
Pre 04/07/1986 CSRS Service	0	0	0
Noncreditable CSRS Service	0	0	0
CSRS Sick Leave	0	0	0
Total Pre 04/07/1986 CSRS Service	0	0	0
Post 04/07/1986 CSRS Service	0	0	0
Noncreditable CSRS Service	0	0	0
Total Post 04/07/1986 CSRS Service	0	0	0
Total CSRS Service Credit	0	0	0
FERS Service Credit	26	0	9
Noncreditable FERS Service	0	0	0
FERS Sick Leave	0	3	23
Total FERS Service Credit	26	4	2
Total Service Credit	26	4	2

### Total Service Includes

	Yrs	Mos	Days
FERS LEO/FF/ATC/CBPO Service	0	0	0
FERS Congressional Service	0	0	0
Total Military Service	0	0	0
CSRS Post-1956 Military Service	0	0	0
CSRS LEO/FF/ATC/CBPO Service	0	0	0
CSRS Congressional Service	0	0	0

### Estimate Basis

Date of Birth	03/28/1953	Retirement System	FERS Regular
Age at Retirement	69 Years 7 Months	Date of Retirement	11/03/2022
Retirement SCD	10/25/1996	Date of Separation	N/A
LEO/FF/ATC SCD	N/A	Sick Leave Hours	652
Spouse's Date of Birth	04/30/1959	Unpaid Pre 10/01/1982 CSRS Deposit	\$0.00
Spouse's Age	63 Years	Unpaid Pre 03/01/1991 CSRS Redeposit	\$0.00
Survivor Benefit Base Elected	100%	FERS Lump-Sum Credit	N/A
FGLI Code	C0	CSRS Lump-Sum Credit	N/A
FEHB Plan Code	106	Deemed High-3 Average Salary	\$312,573.00
Dental Insurance Plan Type	None	Tax Status	Married Filing Jointly/Qualifying Widow(er)
Vision Insurance Plan Type	None	FERS Part-Time Proration Factor	84%
Final Weekly Tour of Duty Hours	40	CSRS Part-Time Proration Factor	N/A

## FERS Benefit Estimate Report CHARLES H ANDRUS

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Notes:

BENEFIT AMOUNTS SHOWN IN THIS REPORT ARE ESTIMATES AND NOT INTENDED TO REPRESENT ACTUAL AMOUNTS. THE OFFICE OF PERSONNEL MANAGEMENT HAS SOLE AUTHORITY AND RESPONSIBILITY FOR ADJUDICATING RETIREMENT CLAIMS. Upon retirement, your retirement application and supporting documentation is submitted to OPM. Upon receipt of your retirement claim, OPM will place you in an interim pay status. Your interim payments will continue until OPM has completed full adjudication of your retirement claim. A FERS service factor of 0.289667, which represents your total service credit for retirement computation purposes, was used in the formula to compute your estimated monthly annuity.

Based on employee's final basic pay of \$320,036 and 41.00 hours of unused annual leave, the gross lump-sum annual leave payment would be \$6,287.35



## FERS Benefit Estimate Report CHARLES H ANDRUS

### Explanation of Annuity Computation

Unreduced Monthly Annuity:	Monthly annuity amount before any reductions. The amount is based on employee's high-3 average salary and total service credit at date of retirement and the applicable CSRS benefit formula.
Annuity Reductions:	
Early Retirement Age:	A reduction of 2.0 percent for each year employee is under age 55 at date of retirement for CSRS early and discontinued service retirement cases and in computing the CSRS component in FERS transferee cases. For FERS early deferred and MRA + 10 retirement cases, a reduction of 5.0 percent for each year the employee is under age 62 at date of retirement.
Unpaid CSRS Deposit:	A reduction equal to 10 percent of the amount of unpaid deposits relating to any creditable CSRS service prior to 10/01/1982 during which employee made no retirement contributions.
Survivor Benefit:	A reduction for the cost of a survivor benefit election. The cost is equal to 10 percent of the base specified for use in computing the benefit.
Unpaid CSRS Redeposit:	A reduction applicable to cases in which employee received a refund of CSRS retirement contributions for a period of service which ended before 03/01/1991 and has elected not to make a redeposit. The reduction is based on the amount of the unpaid redeposit and the employee's age at time of retirement.
Alternative Annuity:	An actuarial reduction that is applied when an employee elects the "Alternative Form of Annuity" (AFA). The amount of the reduction is based on the sum of the employee's total retirement contributions, the total of all unpaid civilian service deposits and CSRS post 02/28/1991 redeposits, and the employee's age at time of retirement.
Gross Monthly Annuity:	Monthly annuity payable after employee's "Unreduced Monthly Annuity" is reduced by the sum of applicable reductions.
Annuity Deductions:	
Health Insurance Premium:	Monthly cost of health plan coverage elected. (See Health Insurance Election, below, for details.)
Life Insurance Premium:	Monthly cost of life insurance coverage elected. (See Life Insurance Election, below, for details.)
Federal Tax Withholding:	Federal tax withholding based on amount of the Gross Monthly Annuity payable, and the filing status elected.
NET MONTHLY ANNUITY:	Monthly annuity payable after employee's "Gross Monthly Annuity" is reduced by the sum of applicable deductions.
FERS Annuity Supplement:	A monthly annuity paid until age 62 (as a substitute for Social Security benefits) to certain FERS employees who retire on an immediate unreduced annuity before age 62. It does not apply in FERS disability cases. Income earned after retirement, that exceeds the "exempt amount", may reduce or eliminate the annuity supplement.
Monthly Survivor Annuity Elected:	Monthly survivor annuity payable based on 50 percent of the base specified for use in computing the annuity. (See Survivor Annuity Alternatives, below, for details.)

### Service Credits

Pre 04/07/1986 CSRS Service:	Total service (civilian and military) creditable performed under CSRS before 04/07/1986 used for purposes of determining eligibility for retirement.
Post 04/06/1986 CSRS Service:	Total service (civilian and military) creditable performed under CSRS after 04/06/1986 used for purposes of determining eligibility for retirement.
Noncreditable Service:	Service that is not creditable and is not used in computing the amount of an annuity. Examples of such service are unpaid post-09/30/1982 deposit service and unpaid post-02/28/1991 redeposit service.
Sick Leave:	Unused sick leave hours are converted into service credit years, months, and days. In transferee cases, the amount of sick leave credit that is applicable (if any) to each component is shown separately.
Total CSRS Service Credits:	Service credits used, when applicable, in computing the CSRS component of employee's annuity.
Total FERS Service Credits:	Service credits used both in determining retirement eligibility and computing employee's FERS annuity.
Total Service Includes:	(Types of FERS and CSRS service included in employee's Total Service Credit, as applicable.)
LEO/FF/ATC/CBPO Service:	Service as a Federal law enforcement officer, firefighter, air traffic controller, or CBP officer.
Total Military Service:	Creditable active duty military service.
Post-1956 Military Service:	Total unpaid military service performed after 1956.
Congressional Service:	Service performed as a Congressional employee.



## FERS Benefit Estimate Report CHARLES H ANDRUS

### Estimate Basis

(The data shown in this section of the Benefit Estimate Report was considered in computing estimate benefits.)

**Date of Retirement:** Date employee separated from Federal service. The annuity commencement date depends on the type of retirement. In Disability and Discontinued Service Retirement cases, the annuity begins the day following the date of retirement. In Optional and Early Retirement cases, the annuity begins on the 1st day of the month following the date of retirement.

**Date of Separation:** This date is applicable only in deferred and postponed retirement cases and is the date employee separated from Federal service. In such cases, the Date of Retirement refers to the date the deferred or postponed annuity will commence.

**FERS/CSRS Lump-Sum Credit:** Employee's total unrefunded FERS and, if applicable, CSRS retirement contributions as of Date of Retirement. The total includes all civilian service deposits, CSRS post 02/28/1991 redeposits, and Post-1956 military service deposits made by employee. The amount is used to compute the nontaxable portion of an annuity and the reduction applied when an Alternative Annuity is elected.

**Deemed High-3 Average Salary:** Employee's highest average salary during any 3 years of consecutive service. The computation is based on actual and or deemed annual rates of pay and the period of time each rate was in effect.

**FERS Part-Time Proration Factor:** A percentage factor based on the ratio of the total hours employee actually worked while covered by FERS to total full-time hours during the same period.

**CSRS Part-Time Proration Factor:** A percentage factor based on the ratio of the total hours employee actually worked between 04/06/1986 and date transferred to FERS to total full-time hours during the same period.

**Final Weekly Tour of Duty Hours:** Used, when applicable, to determine final salary for FEGLI coverage amounts.

**Tax Status:** Shows, if applicable, the basis used to compute Federal Tax Withholding deductions.

### Survivor Annuity Alternatives

Alternative Base	Survivor Annuity	Monthly Cost
Full	\$3,168.00	\$633.79
One-Half	\$1,584.00	\$316.90

The table above shows the monthly amount and cost of a survivor annuity based on the election of a full or one-half survivor annuity.

### Health Insurance

Plan Name	Type	Monthly Premium
Blue Cross and Blue Shield Service Benefit Plan Standard Optio	Standard Self Plus One	\$690.84

(Based on 2023 FEHB rates.)

### Life Insurance

The table below shows the amount of insurance coverage employee elected to continue in retirement and the monthly premium costs, based on 2021 FEGLI rates. Reductions begin at age 65 or date of retirement if later.

Coverage Based On Final Basic Pay Of \$320,036.00		Monthly Premiums					
		Type	At Retirement	At Age 65	At Age 70	At Age 75	At Age 80
Basic	\$323,000.00	Basic					
Option A - Standard	\$0.00	75% Reduction	\$0.00	N/A	N/A	N/A	N/A
Option B - Additional [0 multiples]	\$0.00	50% Reduction	\$242.25	N/A	\$242.25	\$242.25	\$242.25
Total Coverage	\$323,000.00	No Reduction	\$726.75	N/A	\$726.75	\$726.75	\$726.75
Option C - Family [0 multiples]		Option A	\$0.00	N/A	N/A	N/A	N/A
Spouse	\$0.00	Option B [0NR, 0FR]	\$0.00	N/A	N/A	N/A	N/A
Child	\$0.00	Option C [0NR, 0FR]	\$0.00	N/A	N/A	N/A	N/A

Note: Premiums shown at age 65, 70, 75, and 80 for FEGLI Option B and/or Option C are for the number of multiples elected at time of retirement with no reduction. The premiums for the number of multiples elected with full reduction will cease at age 65 or date of retirement if later.

### Dental & Vision Insurance

Plan Name	Type	Monthly Premium
N/A	Dental None	N/A
N/A	Vision None	N/A



No. 27189

Issued at 11:30 A.M.  
THIS LICENSE VALID FOR ONLY  
30 DAYS FROM DATE OF ISSUE.

NOTE: THIS IS A MARRIAGE LICENSE—NOT A MARRIAGE CERTIFICATE. IF IT IS NOT USED,  
THE PERSON TO WHOM IT IS DELIVERED MUST RETURN IT PROMPTLY TO THE COUNTY CLERK AND RE-  
CORDER WHO ISSUED IT.

MISC-1 .00

# MARRIAGE LICENSE

THE STATE OF COLORADO.

CITY AND COUNTY OF DENVER

To any person or religious society Authorized by Law to  
Perform the Marriage Ceremony:

GREETING: You are hereby authorized to join in marriage

Mr. Charles H. Andrus III of St. Louis Missouri and

Ms. Pamela Sue Bergkamp of St. Louis Missouri

and of this license you will make due return to my office.

Witness: my hand and the seal of my office at  
Denver, Colorado

This 24<sup>th</sup> day of July, 1985

Julius M. Tice County Clerk & Recorder

By David F. Ruedell Deputy



## MARRIAGE CERTIFICATE

STATE OF COLORADO,

County of Denver

SS.

It is hereby certified that on the 27<sup>th</sup> day of July  
A.D. 1985 at Most Precious Blood Church  
in said county the undersigned a Catholic Priest  
did join in the Holy Bonds of Matrimony in accordance with the laws  
of the state of Colorado and the authorization of the foregoing license  
Mr. Charles H. Andrus III and  
Ms. Pamela Sue Bergkamp

Witness: my hand and seal the day and year last above written.

Fr. Paul J. Morgan S.J.

Catholic Priest

Official Title

Charles H. Andrus III

Witness

Signed

Charles H. Andrus III

Groom

Mary K. Bergkamp

Witness

Signed

Pamela Sue Bergkamp

Bride

This Certificate, duly executed together with the License, must be returned by the minister or officer who shall have solemnized the  
marriage, to the office of the County Clerk who issued the same, promptly. Penalty provided for failure to do so.

PLEASE USE BROWN OR GREEN INK

046011

07 31 05 AM 11:00

EUGENIA MARKOS  
NOTARY PUBLIC, STATE OF MISSOURI  
MY COMMISSION EXPIRES 9/11/96  
CITY OF ST. LOUIS

ORIGINAL  
COPY OF  
ORIGINAL  
NOTARY  
1-20-86





U.S. Department of Veterans Affairs

Office of Community Care  
Workforce Management

Dept. of Veterans Affairs, VHA-RSSO  
Townsite Plaza II  
120 SE 6<sup>th</sup> Ave, Suite 102  
Topeka, KS 66603

## Memorandum for Record

To: Office of Personnel Management  
Retirement Operations Center  
Boyers, PA

January 31, 2023

To Whom it May Concern:

Mr. Andrus provided additional documentation regarding a discrepancy in his salary. He has spoken to me on numerous occasions stating his efforts to get this issue rectified have been unsuccessful.

If you have any questions or concerns, you may contact our Service Line at (866) 330-7366 Monday through Friday, 7:30am to 4:30pm, CT.

Regards,

A handwritten signature in cursive script that reads "Dara Fairfield".

Dara Fairfield  
Retirement Counselor

150 Emerald Green Court  
St. Louis, MO. 63141  
314-445-9482 or 314-809-9634  
January 29, 2023

Dara Fairfield  
HR Specialist, RSSO/Worklife Benefits SSU  
Human Resources Operations Office, HROO (106A6)  
Workforce Management and Consulting (106A)  
Veterans Health Administration  
U.S. Department of Veterans Affairs  
Office Phone (785) 350-1553

Address:  
120 Southwest 6<sup>th</sup> Avenue  
Suite 102  
Topeka, KS., 66603

As per your request:  
Appendix A: Pamela and Charles Andrus, Marriage / License Certificate,  
July 27, 1985.  
Appendix B: VA forms completed: SF 3107, SF 3107-1, SF 2818, W-4P  
(2023),  
and additionally:

Appendix C: U.S. Department of Veterans Affairs Commendations  
Appendix D: Result of Audit of DFAS

**Re: VA RSSO Case 286816**  
**NIAID Case #122786**

Dear Ms. Fairfield:

Thank you so very much for notifying me on January 11, 2023, of the need for me to submit additional documentation/VA forms regarding my retirement from the Veterans Health Administration (VHA) of the U.S. Department of Veterans affairs. As I told you over the phone at that time, I had submitted a tremendous amount of documentation (~14 lbs.) on September 24th 2022, (including cover letters and e-mails dated September 14, 2022<sup>Book 2: 1-11</sup>, August 24, 2022<sup>Book 2: 13-32</sup>, July 29, 2022<sup>Book 2: 33-100</sup>; and our Marriage Certificate via the U.S. Postal Service as Priority Mail to: the US Department of Veterans affairs (offices of the Secretary of the Department of Veterans Affairs [USPS tracking number: 9410 8036 9930 0153 7266 20], the offices of the General Counsel (and DEAO) per the direction of Michael Hogan, J.D. in our phone conversation in the Spring of 2022 to copy all to the OGC [USPS tracking number: 9410 8036 9930 0153 7266 06]); The National Institute of Allergy and Infectious Diseases as per the establishment of NIAID Case file #12276 [accessible to anyone under the FOIA] by Kara Harris MPH [USPS tracking number: 9410 8036 9930 0153 7286 24] at the direction of the Director,



Anthony Fauci, M.D. [USPS tracking number: [9410 8036 9930 0153 7266 13]; and the U.S. Constitutional-responsible and accountable authority for the Executive Branch of the Federal Government, President Joseph Biden [USPS tracking number: 9410 8036 9930 0153 7265 90]; and a host of others.

As you emphasized several times that you could not find a copy of Pam (my wife) and my marriage certificate / license in the requested submission even though it was submitted to the VA RSSO on ~July 29, 2022, in my submission on September 24th 2022, and again today in my submission of the **paginated** version of the September 24<sup>th</sup> 2022 submission on page 100 of Book 2. Therefore, I will submit again with this electronic e-mail submission to you today another copy of our marriage certificate / license (Appendix I).

In our conversation over the phone a week ago, you also reiterated to me that if my file was not complete by January 31, 2023, the VA would close it on January 31st 2023, and turn it over to the Office of Personnel Management (OPM). As OPM is not a division of the VA but is the payroll site for all Federal employee retirees, you explained that my entire case file would have to be completely reconstituted so as to **appeal my underpayment from August 2016 to November 2022 by the VA** so as to appropriately calculate my pension even though I have contested my Grade and Rank since returning to the VA >6 years ago.<sup>Book 2</sup> I responded to you with my interpretation of that of which you had just stated as a “drop dead date” for the VA to *wash its hands* of my retirement package and dump it on another Federal agency(ies) without the VA reviewing and adjudicating my retirement calculations as Book 2 documents in much detail as possible of my underpayment of salary over the last six years (as I returned to the VHA at the St. Louis VAMC in August 2016 as a Grade 15, Step 7 physician when I was previously a Grade 15, Step 10 physician from 1994 - 2002).

**To demonstrate my due-diligence**, I submitted over the last six months the documentation that is complete on my part consistently expecting the VA to correct my salary of the last 6 years—**BUT** it never happened. Knowing that my very existence in the VA between 1982 and 2002 was reportedly lost and non-verifiable with the reported misplacement of my official hard copy OPF from April 1982 through January 2002, I essentially became **an unperson in the VA and the Federal Government. (An audit of the U.S. Department of Defense’s Dfas would have revealed my previous VA service dates but, as far as I know, that was never performed prior to my announcing my retirement. See Appendix D)** When I returned in August of 2016, my status was that of a “new hire—without any prior VA experience” as a physician grade 15 step 7 and not that of a physician grade 15 step 10 of which I separated from the VA in January of 2002. This was a *de facto* demotion and retaliation by the VA in violation of my previous submission of EEOC No. 210-A3-6145X that was debated on March 3, 2004 in *Andrus v VA*, U.S. Court of Appeals for the Federal Circuit (USCAFC), Docket case: 03-3162.<sup>Book 2: 315</sup> (The SF-50 in Book 2 documenting my initial advancement to a physician, Grade 15, Step 10 was my SF 50 of 07-22-94<sup>Book 2: 268</sup> while I was the Division Chief of Unit II (SLU) General Surgery in Book 2, page 263 (summary of SF 50s) and the SF 50 of 07-22-94<sup>Book 2: 268</sup>).

You will see in the documentation (now with pagination of Book 2) that I will again send to the VA, as my attempt to reconstruct my hard-copy OPF from April 1982 to January 2002 failed as is stated by the St. Louis VAMC HR specialist on November 15, 2016:



“...Kevin—just got back my order form from the national personnel records center—they have no record for Dr. Charles Andrus.” in Book 2, page 217.

As such as per 38 USC Sec. 7431, CH 74-Personnel, page 958, (Can be found in Book 2, page 194), I am now >25 years of service (See also Appendix C) and thus should be classified regarding rate of base pay Grade 15, Step 13. This clarification of base pay rate is extremely important as this confirms underpayment from August 2016 to the present. A Federal Pension is calculated by an averaging of the three highest paid contiguous years and as I have been underpaid since 2016 as I was initially classified as a “new hire” by the St. Louis VAMC HR and they could not locate my hard-copy OPF from 1982 to 2016. Any pension calculation using the last 36 months of my existence in the VHA at the St. Louis VAMC is a gross under-calculation.

Also, because my hardcopy OPF from 1982 to 2002 was reportedly misplaced (can't be found), the VA SCD on my paychecks for most of the last six was not that which was finally reported on my the last several months of service: 10/25/1997. Also, since my hard-copy opf of 1982-2002, could not be found over the last 6 years, the VA has ignored my accrued 1185.25 hours sick leave from 1986 to 2002. In the recent SF 3107-1 you sent me complete, **box 7** contains a corrected SCD of 10/25/1996 which I assume corrects for my total accrued sick leave towards my pension calculation from 1986 to the present of approximately 1 year (+25 years)—thank you for correcting this.

On January 12, 2023, I called you in response to your voicemail recording on my wife, Pam's, cell phone:

Hi Pamela, this is Dara Fairfield with the Department of Veteran Affairs. I was calling —have been trying to get a hold of Charles regarding his retirement. We are still missing all of his paperwork we never received that back when he had changed his retirement date. So, I am desperately trying to get in touch with him. If you can please have him give me a call back at xxx-xxx-1553, I am headed out for the day; but I will be back tomorrow starting at 6am central standard time, so I look forward to hearing from you guys. Just want to make sure we get him taken care of with his retirement so he can start getting paid. So talk to you guys soon--thank you.

Ms. Fairfield, you first contacted me by e-mail on July 5, 2022, with .pdf attachments that were introductory to the VA retirement system. On January 9, 2023, you sent me an e-mail with additional forms I will be sending back today to you filled-out: 3107.pdf, 2818.pdf, W-4P.pdf, and 3107-1.pdf (3107-2.pdf is not applicable as we discussed last week). [I called you with my wife's SSN as you stated that you already had my SSN].

In our phone conversation last week, you corrected my interpretation of your statement that if all was not completed by January 31, 2023, VA RSSO would close my file turning over to OPM which would have necessitated the initiation of a whole new discovery process.—I interpreted you statement and verbalized to you that, no matter what, on January 31, 2023, if the VA RSSO and the U.S. Department of Veterans Affairs close my case, then they would be “washing their hands of me (after officially >25 years of service)” as your statement implied **my “drop dead date” with the VA**. You responded that: Yes, we have to close your case on January 31, 2023, and then OPM will have to reconstruct everything. In short, another agency of the Federal Government will have to do what the VA should have done over the last six years.



As I have discussed with you several previous times, the reason why the VA lost my paper-copy of my OPF from 1982 to 2002 is because I alleged that while I was the Chief of Surgery, Edward Hines, Jr. VAH, Maywood (Chicago's tertiary VA hospital), IL, the VISN 12 Director called for my firing without cause 12 times as related to me during my deposition by the VA OIG HR specialist in the preparation of the: COMBINED ASSESSMENT PROGRAM REVIEW, EDWARD HINES, JR. VA HOSPITAL, HINES, IL, Report No. 99-00173-18, November 22, 1999. [Please note that the OIG presented to my Hines VAH office in October 1999 requesting documentation of the staffing of the Hines VAH OR and the documentation from page 43 through 61 of the CAP report #99-00173-18 was my work summary of the OR directed to the Director of the Edward Hines, Jr. VAH and my name is un-REDACTED on page 44.] Not only is a **Constructive Discharge** a prohibitive personnel practice, as alleged in "section 45 Remarks" in the SF 50 of 01/19/2002, illegal; but an EEOC Complaint was filed by me before the EEOC [EEOC No. 210-A3-6145X, Agency No. 200K-1886] and the MSPB resulting in the docketing by the U.S. Federal Court of Appeals for the Federal Circuit (USCAFC) in *Andrus v VA*, Case# 03-3162 with Oral Arguments on 3/3/2004. The U.S. Court of Appeals for the Federal Circuit failed to rule *per curiam*, but resultant to *Andrus v VA*, the phrase: **Level 3: Attending Not Present, immediately available** has been changed over the last 20 years in VHA Handbook 1400.1. The URL of the VHA Handbook was changed by the VA to 1400.01 so that the changes would be difficult to legally discover. Most of all, Attending Surgeon supervision of residents in VA Operating Rooms no longer permits or condones Attending Surgeons staffing VA OR cases in physical absentia (Ghost Surgery). ONCE again, Ghost Surgery **is no longer permitted nor condoned by the Veterans Health Administration.**

*Andrus v VA*, USCAFC Case# 03-3162, was initiated through the U.S. MSPB and the U.S. EEOC processes and when I returned to the VA in August 2016, I suffered a *de facto* demotion from a Physician Grade 15, Step 10 to a Physician Grade 15, Step 7 as "The rate of base pay is the rate payable for:" a specific Step (38 USC Sec. 7431, CH 74-Personnel, page 958). I allege that my *de facto* demotion in August 2016 (to Grade 15, Step 7) and all subsequent promotions to a Grade 15, Step 10 last August 2022, **are** wrong and resulted in an underpayment of my biweekly salary for the last 6+ years through the U.S. Department of Defense (DFAS) with full knowledge of individuals within the Veterans Health Administration of the U.S. Department of Veterans Affairs. I allege that listed above is consistent with a **8<sup>th</sup> possible EEOC discriminatory complaint** as I "...believe that I [you] have been discriminated against because of opposing a prohibited practice or participating in an equal employment opportunity matter..." Knowing that the VA pension is calculated by VA RSSO as the average of the highest 3-year continuous salaries, there is no way my pension can be calculated appropriately by VA RSSO until a legally U.S. Department of Veterans Affairs responsible / accountable **AUTHORITY** adjudicates my last 6 years salaries with a summation of legally appropriate Basic Pay and with my locality/market ADJ pay on my previous paychecks. Ms. Fairfield, since you conceded that you could not provide such adjudication, it would seem such a process is within the scope of our VA superiors, e.g.: the Under Secretary of Health, Veterans Health Administration, or the Secretary of the U.S. Department of Veterans Affairs. For the VA through the RSSO to dump my "closed-out file on January 31, 2023" to DFAS and then OPM without resolution of my appropriate pension based on corrected salaries according to 38 U.S.C. Sec. 7431, CH. 74-Personnel, 958, is unconscionable, probably a violation of Title VII of the Civil Rights Act (Title



VII), and dereliction to duty and consistent with obstruction of justice by all involved in the case of **Andrus v VA**, USCAFC Case# 03-3162, in the VA, DOJ, and OSC.

In summary, this is my understanding of the calculations for adjudication of a correct Gross Monthly Pension allocation:

1. Total number of years: In my case 25 years + ~1 year for accrued sick leave from 1982 to 2022: **SCD of 10/25/1996.**
2. Calculation of FERS Proration factor from Part-time and Full-time service:

From my calculated proration by the Edward Hines, Jr. VAH HR: "FERS Part-Time Employee Data" in 2001 and my Full-Time for the last 6 years from:

- A. (1) FERS service credit: 18 years 8 months 23 days (18.72 years)  
(2) FERS Part-time PRORATION Factor 81.0%
- B. (1) FERS service credit: 6 years 3 months and 27 days. (6.3 years)  
(2) FERS Full-time PRORATION Factor 100.0%

Total: 25 years 0 months 20 days. (~25.05 years)

$$X = \frac{(81.0\% / 18.72) + (100\% * 6.3)}{25.05} = 85.7\%$$

3. As my years of service are >20 years, one will multiple by 1.1
4. **Unfortunately, a VA authority should correct and adjudicate my salaries from August 2016 to the present based on correction of my Base salary in 2016 from the erroneous Grade 15, Step 7 to that which should have been in 2016 of Grade 15, Step 10 in continuation from 2002. Once the biweekly gross salaries from 2016 onward are recalculated regarding base salary, the last 3 years can be averaged and then:**

Averaged Adjusted Base Salary = Base salary + Location salary

Annual Pension Gross Salary should =

Averaged Adjusted Base Salary \* proration of 85.7% \* 1.1

Thus, Ms Fairfield, before the VA RSSO "closes my case" and transmits it to DFAS and OPM, **I plead with you that the above adjudication process and calculations should be completed by the VA before closing my case.** As the forms that are to be returned to you today by e-mail were brought to my attention on January 9, 2023, I would assume that the "Drop Dead date" for the VA RSSO to close my **completed retirement package** is ~60 days from January 9, 2023 (~March 10, 2023). As per my previous submission methodology of September 24, 2022, all

will be submitted through by U.S. Postal Service Priority Mail so it is trackable by the U.S. Postal Inspectors, and discoverable to the general U.S. public through a formal FOIA request of that which I will submit to the NIH NIAID case file #12276: this letter and its Appendices; a hard copy of Book 2, a hard copy of Book 3, and (to be sent later, a copy of Book 1) on a SDHC 16 GB card with all included so as to electronically searchable.

Ms Fairfield, I thank you very much for you past direction; but as you have informed me several times on the phone, you do not have the authority to adjudicate my Grade and Steps over the course of the last 6 years which, at present, are in error and thus an averaging over the highest three continuous years is impossible. As none of your supervisors have stepped up to the plate, I will continue to copy to the Office of General Counsel as per the directions of Michael Hogan, J.D. who previously was one of the members of the Office of VA General Counsel as the Designated Agency Ethics Officer (DAEO); to Secretary McDonough as he is the VA's chief authority; and to President Biden as he is the Head of the Executive Branch of the Federal Government as designated by the U.S. Constitution.

Please review in detail this letter and ask of someone of authority in the U.S. Department of Veterans Affairs to adjudicate my requested review of the last six years to get my Grade and Steps corrected so an appropriate continuous salary of the last 3 consecutive years can be averaged in the calculation of my pension by VA RSSO?

Thank you,

Charles H. Andrus, M.D., F.A.C.S.  
Former Physician and Surgeon, Veterans Health Administration  
U.S. Department of Veterans Affairs  
Former Professor of Surgery, Department of Surgery Saint Louis University SOM  
Former Professor of Surgery, Department of Surgery, Loyola University (Chicago) SOM  
Interviewee for the position of Under Secretary for Health, Veterans Health Administration,  
U.S. Department of Veterans Affairs on December 10, 1999, along with:  
Thomas Bowen, M.D., F.A.C.S. (MG, retired),  
Thomas Garthwaite, M.D.,  
Robert Petzel, M.D., and  
Robert Roswell, M.D.

Federal Whistle Blower in *Andrus v VA*, USCAFC Case #03-3162 with the concurrence and direction in 2001 of Micheal Staley, VA OIG, and James McManus, M.D., F.A.C.S., VHA Medical Inspector (U.S. Office of Special Counsel files: MA-00-1107 and DI- \_\_\_\_\_)



Cc:

Catherine Mitrano, J.D., and Michael R. Hogan, J.D.  
Office of General Counsel (26)  
Designated Agency Ethics Official (DAEO)  
810 Vermont Ave, N.W.  
Washington, D.C. 20420  
Phone: 202-360-2598  
**Re: NIH NIAID Case #12276**

Anthony S. Fauci, M.D.  
Director of the U.S. National Institute of Allergy and Infectious Diseases  
U.S. National Institutes of Health  
U.S. Department of Health & Human Services  
5601 Fishers Lane, MSC. 9806  
Bethesda, MD 20892-9806  
Phone: 301-496-5717 (last varified July 2020)  
FAX: 301-402-3573 (last varified July 2020)  
**Re: NIH NIAID Case #12276**

The Honorable Denis McDonough  
Secretary, U.S. Department of Veterans Affairs  
810 Vermont Ave, NW  
Washington, D.C. 20420  
[Denis.McDough@va.gov](mailto:Denis.McDough@va.gov)  
**Re: NIH NIAID Case #12276**

Abigail Carlson, M.D.  
Centers for Diseases Control/DDID/NCEZID/DHQP/OD  
1600 Clifton Road, Rm 3139  
Atlanta, GA. 30333  
404-718-8458  
[qqd6@cdc.gov](mailto:qqd6@cdc.gov)  
**Re: NIH NIAID Case #12276**

Kara Harris, MPH  
Section Chief for Controlled Correspondence and Public Inquires  
Legislative Affairs and Correspondence Management Branch  
Office of Communications and Government Relations  
U.S. National Institute of Allergy and Infectious Diseases  
U.S. National Institutes of Health  
U.S. Department of Health & Human Services  
5601 Fishers Lane, MSC. 9806, Room 6F30  
Bethesda, MD 20892-9806  
[Kara.Harris@nih.hhs.gov](mailto:Kara.Harris@nih.hhs.gov)  
Phone: 240-627-3693  
**Re: NIH NIAID Case #12276**

**Index of Appendices: Tonight January 29, 2023, I will attach the following Appendices to the transmitted e-mail:**

Appendix A: Pamela and Charles Andrus, Marriage / License Certificate.  
July 27, 1985.

Appendix B: VA forms completed: SF 3107, SF 3107-1, SF 2818, W-4P  
(2023),  
and additionally:

Appendix C: U.S. Department of Veterans Affairs Commendations  
Appendix D: Result of Audit of DFAS

**Due to oversize, my final submission of Books 2 and 3 converted into a pdf format with pagination (Which I sent on 9/24/2022 without page numbers) will be mailed by USPS over the next several days to VA RSSO, VA General Counsel and Secretary McDonough, the NIAID, etc.**



From: Adam Petersen@va.gov  
 To: candrus800@aol.com  
 Cc: Jill Vaughn2@va.gov, Charles Andrus@va.gov  
 Subject: RE: [EXTERNAL] Response to Mr. Petersen regarding Andrus Grade 15, Step 10 in 2002  
 Date: Fri, Jul 1, 2022 1:38 pm

## Attachments:

Dr. Andrus,

Appears all time has been accounted for and is being reflected as PIF. I have mailed you all the information regarding the PIF letter and service dates that OPM uses for calculation. They are quite accurate and complete. If you believe there is service time unaccounted for then I would be involved with that portion after you review these screens and what is delivered in the mail. Otherwise, my role would be complete. Anything pay related is not my lane or area of expertise. Anything retirement related must be handled through the RSSO at 866-330-7366.

This accounts for every day you have been employed as a federal employee since 4/8/1982.

From	To	Agency	Service Type	Retirement System	Status	Show All Details
04/08/1982	09/30/1982	VAMC STL	Regular	FICA Only	Paid	✱ ☐ ▼
10/01/1982	06/30/1986	VAMC STL	Regular	FICA Only	Paid	✱ ☐ ▼
07/01/1986	12/31/1986	VAMC STL	Regular	CSRS Offset		✱ ☐ ▼
01/01/1987	03/07/1996	VAMC STL	Regular	FERS		✱ ☐ ▼
08/18/1996	01/19/2002	VAMC Hines	Regular	FERS		✱ ☐ ▼
08/07/2016	Present	STL VA	Regular	FERS		✱ ▼

From	To	Agency	Service Type	Retirement System	Status	Show All Details
04/08/1982	09/30/1982	VAMC STL	Regular	FICA Only	Paid	✱ ☐
Service Details						
From	To	Work Schedule	Type	Amount	Pay Type	Pay Rate
04/08/1982	06/30/1982	Full-time				
07/01/1982	09/30/1982	LWOP	Bi-weekly TOD	80		

10/01/1982	06/30/1986	VAMC STL	Regular	FICA Only	Paid	✱ ☐
Service Details						
From	To	Work Schedule	Type	Amount	Pay Type	Pay Rate
10/01/1982	06/30/1983	LWOP	Bi-weekly TOD	80		
07/01/1983	09/30/1983	Full-time				
10/01/1983	09/30/1984	LWOP	Bi-weekly TOD	80		
10/01/1984	12/31/1984	Full-time				
01/01/1985	12/31/1985	LWOP	Bi-weekly TOD	80		
01/01/1986	03/31/1986	Full-time				
04/01/1986	06/30/1986	LWOP	Bi-weekly TOD	80		

Response to Mr. Petersen regarding Andrus Grade 15, Step 10 in 2002

07/01/1986	12/31/1986	VAMC STL	Regular	CSRS Offset		
<b>Service Details</b>						
From	To	Work Schedule	Type	Amount	Pay Type	Pay Rate
07/01/1986	12/31/1986	Part-time	Biweekly TOD	70		

01/01/1987	08/17/1995	VAMC STL	Regular	FERS		
<b>Service Details</b>						
From	To	Work Schedule	Type	Amount	Pay Type	Pay Rate
01/01/1987	06/30/1987	LWOP	Biweekly TOD	70		
07/01/1987	01/26/1996	Part-time Title 38	Biweekly TOD	70		
01/27/1996	08/17/1996	Part-time Title 38	Biweekly TOD	50		

08/18/1996	01/19/2002	VAMC Hines	Regular	FERS		
<b>Service Details</b>						
From	To	Work Schedule	Type	Amount	Pay Type	Pay Rate
08/18/1996	01/03/1996	Part-time Title 38	Biweekly TOD	60		
01/04/1996	01/19/2002	Part-time Title 38	Biweekly TOD	70		

08/07/2016 Present STL VA Regular FERS

Work Schedule Full-time

Biweekly TOD 80

Work Schedule Effective Date 08/07/2016

Non-Federal Service Creditable for Leave Accrual 0 Years 0 Months 0 Days

CSRS Special Service Abroad 0 Years 0 Months

FERS Special Service Abroad 0 Years 0 Months

FSRDS Unhealthful Post Service 0 Years 0 Months 0 Days

From: Candrus600 <candrus600@aol.com>

Sent: Friday, July 1, 2022 9:19 AM

To: Petersen, Adam J. CMOVAMC <Adam.Petersen@va.gov>

Cc: Majerus, Brandi L. <Brandi.Majerus@va.gov>; Vaughn, Jill M. (STL) <Jill.Vaughn2@va.gov>; Andrus, Charles H. (STL) <Charles.Andrus@va.gov>; Candrus600 <candrus600@aol.com>

Subject: [EXTERNAL] Response to Mr. Petersen regarding Andrus Grade 15, Step 10 in 2002

July 1, 2022

Dear Mr. Petersen:

was the Chief of Surgery, Surgical Service, Edward Hines, Jr. VAH in Maywood, IL (the Chicago tertiary VAMC) from 1996 to 2002. My final SF-50 of 1/19/2002 documents my Grade 15, Step 10. Also, my payroll stubs of the time document this plus that I had accrued 1158.25 hours of sick leave when I separated from the VA in January 2002. Also, could you please look into when I transferred from CSRS to FERS since I began under CSRS and I am not sure that I ever signed the document to transfer into FERS in the late 1980s which would mean that my continuous service from April 8, 1962 to August 1996 at the St. Louis VAMC should be under CSRS and not FERS. From August 1996 to January 2002, I had transferred to the Edward Hines, Jr. VAH to become





# 2019 VA St. Louis Medical Staff Award



**Michael Lippman, MD**

Dr. Lippmann has been a pillar of strength and high-quality patient care at the St. Louis VA for 28 years. He maintains the highest clinical care and teaching standards, and his patients and students are devoted to him. Dr. Lippmann consistently takes on additional clinical work often without being asked. He, along with 2 other members of the pulmonary division, elected to take over all the daytime physician care in the medical intensive care unit until the hospitalist service was expanded ~1 decade ago. Dr. Lippmann served as the acting ER director until Dr. Fieg arrived, covering many shifts, and continued to do so during a severe physician shortage. Dr. Lippmann maintains the highest level of enthusiasm for what he does, and always is willing to provide advice on patient care when asked. He places the good of the institutional ahead of his own interests, and the St. Louis VA owes him a great deal. He is nominated for excellence in patient care, teaching, and integrity.



**Charles H. Andrus, MD, FACS**

Dr. Andrus is a staff physician in the Surgical Service's Section of General Surgery is recognized by his peers for his excellence in patient care, teaching, integrity, and research. He has over 20 years of service in VHA, and the majority of that time has been dedicated to the care of our Veterans at the John Cochran VA. Dr. Andrus is an experienced researcher and clinician and has served on numerous committees and in many leadership roles. His peers praise him for "instilling a passion for surgery in his residents" and "teaching residents how to care for patients at the bedside". He has played an integral role in the day to day function and coverage of general surgery clinical services and is known for his multidisciplinary approach to patient care and commitment to considering the biopsychosocial needs of his patients. He has continued to deliver the highest quality of care to our Veterans and his colleagues and patients alike have benefited greatly from his knowledge, experience, compassion, and dedication.

# Department of Veterans Affairs

## Commendation

*This certificate is awarded to*

**CHARLES H. ANDRUS, M.D.**

The Hospital Ethics Committee (HEC) awards this Commendation to Charles H. Andrus, M.D., Chief, Surgical Service, Edward Hines Jr. VA Hospital and Professor of Surgery, Loyola University Stritch School of Medicine in recognition of his extraordinary courage, dedication and contributions to ethical practices in healthcare. In clinical practice and as the Chief of Surgical Service, Dr. Andrus has been an exemplary ethical practitioner and leader. As a clinician, he has been a forthright advocate of the need for compassionate, respectful and candid dialogue between patients, their family members and caregivers regarding the moral tensions and emotional turmoil that often arise at the end-of-life. His sensitivity to and advocacy for these issues and the delicate mediation and decision-making they require have been inspirational. Furthermore, in every respect, he has been an outspoken, articulate and passionate champion of the need for constant vigilance about the ethical implications of physician practices. In a most effective way, his leadership style has been his example. The entire hospital community is indebted to him for the impact that he has had on our patients and their family members. He is looked upon with great respect and held in great esteem by his colleagues who have been honored by his presence. As a result of his admirable qualities, it is with great pleasure that the HEC commends Dr. Andrus for his inspirational contributions and leadership. We wish him well and God's speed in his new endeavors.



A handwritten signature in black ink, appearing to read "Barbara Temeck".

BARBARA TEMECK, M.D.  
CHIEF OF STAFF

GERALD J. MOZDZIERZ, Ph.D.  
CHAIRMAN, HOSPITAL ETHICS  
COMMITTEE



# Department of Veterans Affairs



## Certificate of Retirement

*Honoring*

**Charles H. Andrus, M.D.**

*In recognition of your retirement from the  
Department of Veterans Affairs.*

*Thank you for your dedicated service to the  
Government of the United States of America.*

*Given this November 3, 2022  
at the VA St. Louis Health Care System*



A handwritten signature in dark ink, appearing to read "Fabian Grabski", written over a horizontal line.

**FABIAN GRABSKI**

Acting Medical Center Director  
VA St. Louis Health Care System



# Department of Veterans Affairs



## Service Award

*Presented to*

**Charles H. Andrus, M.D.**

*in appreciation of your 25 years of dedicated  
service to the United States Government.*

*Given at VA St. Louis Health Care System*

*October 25, 2022*



A handwritten signature in dark ink, appearing to read "Fabian Grabski", written over a horizontal line.

**FABIAN GRABSKI**  
Acting Medical Center Director



Form **W-4P**  
Department of the Treasury  
Internal Revenue Service

# Withholding Certificate for Periodic Pension or Annuity Payments

OMB No. 1545-0074

**2023**

Give Form W-4P to the payer of your pension or annuity payments.

<b>Step 1:</b> Enter Personal Information	(a) First name and middle initial <b>CHARLES</b>	Last name <b>H ANDRUS</b>	(b) Social security number <b>563-94-2723</b>
	Address <b>150 Emerald Green Ct</b>		
	City or town, state, and ZIP code <b>St. Louis, MO 63141-7541</b>		
	(c) <input type="checkbox"/> Single or Married filing separately <input checked="" type="checkbox"/> Married filing jointly or Qualifying surviving spouse <input type="checkbox"/> Head of household (Check only if you're unmarried and pay more than half the costs of keeping up a home for yourself and a qualifying individual.)		

Complete Steps 2-4 ONLY if they apply to you; otherwise, skip to Step 5. See pages 2 and 3 for more information on each step and how to elect to have no federal income tax withheld (if permitted).

<b>Step 2:</b> Income From a Job and/or Multiple Pensions/ Annuities (Including a Spouse's Job/ Pension/ Annuity)	Complete this step if you (1) have income from a job or more than one pension/annuity, or (2) are married filing jointly and your spouse receives income from a job or a pension/annuity. See page 2 for examples on how to complete Step 2.
	Do only one of the following.
	(a) Reserved for future use.
	(b) Complete the items below.
	(i) If you (and/or your spouse) have one or more jobs, then enter the total taxable annual pay from all jobs, plus any income entered on Form W-4, Step 4(a), for the jobs less the deductions entered on Form W-4, Step 4(b), for the jobs. Otherwise, enter "-0-" <b>\$ 0</b> (ii) If you (and/or your spouse) have any other pensions/annuities that pay less annually than this one, then enter the total annual taxable payments from all lower-paying pensions/annuities. Otherwise, enter "-0-" <b>\$ 55,000</b> (iii) Add the amounts from items (i) and (ii) and enter the total here <b>\$ 55,000</b>
<b>TIP:</b> To be accurate, submit a new Form W-4P for all other pensions/annuities if you haven't updated your withholding since 2021 or this is a new pension/annuity that pays less than the other(s). Submit a new Form W-4 for your job(s) if you have not updated your withholding since 2019. If you have self-employment income, see page 2.	

Complete Steps 3-4(b) on this form only if (b)(i) is blank and this pension/annuity pays the most annually. Otherwise, do not complete Steps 3-4(b) on this form.

<b>Step 3:</b> Claim Dependent and Other Credits	If your total income will be \$200,000 or less (\$400,000 or less if married filing jointly):	
	Multiply the number of qualifying children under age 17 by \$2,000 <b>\$</b>	
	Multiply the number of other dependents by \$500 <b>\$</b>	
	Add other credits, such as foreign tax credit and education tax credits <b>\$</b>	
	Add the amounts for qualifying children, other dependents, and other credits and enter the total here <b>3 \$</b>	
<b>Step 4 (optional):</b> Other Adjustments	(a) Other income (not from jobs or pension/annuity payments). If you want tax withheld on other income you expect this year that won't have withholding, enter the amount of other income here. This may include interest, taxable social security, and dividends <b>4(a) \$</b>	
	(b) Deductions. If you expect to claim deductions other than the basic standard deduction and want to reduce your withholding, use the Deductions Worksheet on page 3 and enter the result here <b>4(b) \$</b>	
	(c) Extra withholding. Enter any additional tax you want withheld from each payment <b>4(c) \$</b>	
<b>Step 5:</b> Sign Here	<b>Charles H. Andrus MD</b> Your signature (This form is not valid unless you sign it.)	<b>01/22/2023</b> Date



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### Publications

The publications listed offer more detailed information about their respective topics. These publications and additional information can be found through the Office of Personnel Management (OPM) website [www.opm.gov/retire/pubs/index.asp](http://www.opm.gov/retire/pubs/index.asp). You can also obtain copies of the publications by contacting OPM directly at toll-free 1-888-767-6738 (TTY: 1-800-878-5707), e-mailing to [retire@opm.gov](mailto:retire@opm.gov), or writing to OPM at the U.S. Office of Personnel Management Federal Employees Retirement System P.O. Box 45 Boyers, PA 16017-0045.

Title	Publication Number
Information for Annuitants (CSRS)	RI 20-59
Information for Annuitants (FERS)	RI 90-8
Information for Disability Annuitants (CSRS)	RI 25-26
Information for Disability Annuitants (FERS)	RI 98-2
Life Events and Your Retirement and Insurance Benefits for Annuitants	RI 38-126
Information for Survivor Annuitants (CSRS)	RI 25-26
Information for Survivor Annuitants (FERS)	RI 90-12
Information for Retirees About the Federal Employees Group Life Insurance Program (FEGLI)	RI 76-12
Information for Retirees About the Federal Employees Health Benefits Program (FEHB)	RI 79-2



150 Emerald Green Court  
St. Louis, MO. 63141  
314-445-9482 or 314-809-9634  
January 29, 2023

Dara Fairfield  
HR Specialist, RSSO/Worklife Benefits SSU  
Human Resources Operations Office, HROO (106A6)  
Workforce Management and Consulting (106A)  
Veterans Health Administration  
U.S. Department of Veterans Affairs  
Office Phone (785) 350-1553

Address:  
120 Southwest 6<sup>th</sup> Avenue  
Suite 102  
Topeka, KS., 66603

As per your request:  
Appendix A: Pamela and Charles Andrus, Marriage / License Certificate,  
July 27, 1985.  
Appendix B: VA forms completed: SF 3107, SF 3107-1, SF 2818, W-4P  
(2023),  
and additionally:

Appendix C: U.S. Department of Veterans Affairs Commendations  
Appendix D: Result of Audit of DFAS

**Re: VA RSSO Case 286816**  
**NIAID Case #122786**  
**ERROR. Should be NIH NIAID Case# 12276 corrected on 2/16/2023**

Dear Ms. Fairfield:

Thank you so very much for notifying me on January 11, 2023, of the need for me to submit additional documentation/VA forms regarding my retirement from the Veterans Health Administration (VHA) of the U.S. Department of Veterans affairs. As I told you over the phone at that time, I had submitted a tremendous amount of documentation (~14 lbs.) on September 24th 2022, (including cover letters and e-mails dated September 14, 2022<sup>Book 2: 1 - 11</sup>, August 24, 2022<sup>Book 2: 13 - 32</sup>, July 29, 2022<sup>Book 2: 33-100</sup>; and our Marriage Certificate via the U.S. Postal Service as Priority Mail to: the US Department of Veterans affairs (offices of the Secretary of the Department of Veterans Affairs [USPS tracking number: 9410 8036 9930 0153 7266 20], the offices of the General Counsel (and DEAO) per the direction of Michael Hogan, J.D. in our phone conversation in the Spring of 2022 to copy all to the OGC [USPS tracking number: 9410 8036 9930 0153 7266 06]); The National Institute of Allergy and Infectious Diseases as per the establishment of NIAID Case file #12276 [accessible to anyone under the FOIA] by Kara Harris



MPH [USPS tracking number: 9410 8036 9930 0153 7286 24] at the direction of the Director, Anthony Fauci, M.D. [USPS tracking number: [9410 8036 9930 0153 7266 13]; and the U.S. Constitutional-responsible and accountable authority for the Executive Branch of the Federal Government, President Joseph Biden [USPS tracking number: 9410 8036 9930 0153 7265 90]; and a host of others.

As you emphasized several times that you could not find a copy of Pam (my wife) and my marriage certificate / license in the requested submission even though it was submitted to the VA RSSO on ~July 29, 2022, in my submission on September 24th 2022, and again today in my submission of the **paginated** version of the September 24<sup>th</sup> 2022 submission on page 100 of Book 2. Therefore, I will submit again with this electronic e-mail submission to you today another copy of our marriage certificate / license (Appendix I).

In our conversation over the phone a week ago, you also reiterated to me that if my file was not complete by January 31, 2023, the VA would close it on January 31st 2023, and turn it over to the Office of Personnel Management (OPM). As OPM is not a division of the VA but is the payroll site for all Federal employee retirees, you explained that my entire case file would have to be completely reconstituted so as to **appeal my underpayment from August 2016 to November 2022 by the VA** so as to appropriately calculate my pension even though I have contested my Grade and Rank since returning to the VA >6 years ago.<sup>Book 2</sup> I responded to you with my interpretation of that of which you had just stated as a “drop dead date” for the VA to *wash its hands* of my retirement package and dump it on another Federal agency(ies) without the VA reviewing and adjudicating my retirement calculations as Book 2 documents in much detail as possible of my underpayment of salary over the last six years (as I returned to the VHA at the St. Louis VAMC in August 2016 as a Grade 15, Step 7 physician when I was previously a Grade 15, Step 10 physician from 1994 - 2002).

**To demonstrate my due-diligence**, I submitted over the last six months the documentation that is complete on my part consistently expecting the VA to correct my salary of the last 6 years—**BUT** it never happened. Knowing that my very existence in the VA between 1982 and 2002 was reportedly lost and non-verifiable with the reported misplacement of my official hard copy OPF from April 1982 through January 2002, I essentially became **an unperson in the VA and the Federal Government. (An audit of the U.S. Department of Defense’s Dfas would have revealed my previous VA service dates but, as far as I know, that was never performed prior to my announcing my retirement. See Appendix D)** When I returned in August of 2016, my status was that of a “new hire—without any prior VA experience” as a physician grade 15 step 7 and not that of a physician grade 15 step 10 of which I separated from the VA in January of 2002. This was a *de facto* demotion and retaliation by the VA in violation of my previous submission of EEOC No. 210-A3-6145X that was debated on March 3, 2004 in *Andrus v VA*, U.S. Court of Appeals for the Federal Circuit (USCAFC), Docket case: 03-3162.<sup>Book 2: 315</sup> (The SF-50 in Book 2 documenting my initial advancement to a physician, Grade 15, Step 10 was my SF 50 of 07-22-94<sup>Book 2:268</sup> while I was the Division Chief of Unit II (SLU) General Surgery in Book 2, page 263 (summary of SF 50s) and the SF 50 of 07-22-94<sup>Book 2: 268</sup>).

You will see in the documentation (now with pageation of Book 2) that I will again send to the VA, as my attempt to reconstruct my hard-copy OPF from April 1982 to January 2002 failed as is stated by the St. Louis VAMC HR specialist on November 15, 2016:

“...Kevin—just got back my order form from the national personnel records center—they have no record for Dr. Charles Andrus.” in Book 2, page 217.

As such as per 38 USC Sec. 7431, CH 74-Personnel, page 958, (Can be found in Book 2, page 194), I am now >25 years of service (See also Appendix C) and thus should be classified regarding rate of base pay Grade 15, Step 13. This clarification of base pay rate is extremely important as this confirms underpayment from August 2016 to the present. A Federal Pension is calculated by an averaging of the three highest paid contiguous years and as I have been underpaid since 2016 as I was initially classified as a “new hire” by the St. Louis VAMC HR and they could not locate my hard-copy OPF from 1982 to 2016. Any pension calculation using the last 36 months of my existence in the VHA at the St. Louis VAMC is a gross under-calculation.

Also, because my hardcopy OPF from 1982 to 2002 was reportedly misplaced (can’t be found), the VA SCD on my paychecks for most of the last six was not that which was finally reported on my the last several months of service: 10/25/1997. Also, since my hard-copy opf of 1982-2002, could not be found over the last 6 years, the VA has ignored my accrued 1185.25 hours sick leave from 1986 to 2002. In the recent SF 3107-1 you sent me complete, **box 7** contains a corrected SCD of 10/25/1996 which I assume corrects for my total accrued sick leave towards my pension calculation from 1986 to the present of approximately 1 year (+25 years)—thank you for correcting this.

On January 12, 2023, I called you in response to your voicemail recording on my wife, Pam’s, cell phone:

Hi Pamela, this is Dara Fairfield with the Department of Veteran Affairs. I was calling –have been trying to get a hold of Charles regarding his retirement. We are still missing all of his paperwork we never received that back when he had changed his retirement date. So, I am desperately trying to get in touch with him. If you can please have him give me a call back at xxx-xxx-1553, I am headed out for the day; but I will be back tomorrow starting at 6am central standard time, so I look forward to hearing from you guys. Just want to make sure we get him taken care of with his retirement so he can start getting paid. So talk to you guys soon--thank you.

Ms. Fairfield, you first contacted me by e-mail on July 5, 2022, with .pdf attachments that were introductory to the VA retirement system. On January 9, 2023, you sent me an e-mail with additional forms I will be sending back today to you filled-out: 3107.pdf, 2818.pdf, W-4P.pdf, and 3107-1.pdf (3107-2.pdf is not applicable as we discussed last week). [I called you with my wife’s SSN as you stated that you already had my SSN].

In our phone conversation last week, you corrected my interpretation of your statement that if all was not completed by January 31, 2023, VA RSSO would close my file turning over to OPM which would have necessitated the initiation of a whole new discovery process.—I interpreted you statement and verbalized to you that, no matter what, on January 31, 2023, if the VA RSSO and the U.S. Department of Veterans Affairs close my case, then they would be “washing their hands of me (after officially >25 years of service)” as your statement implied **my “drop dead**

**date” with the VA.** You responded that: Yes, we have to close your case on January 31, 2023, and then OPM will have to reconstruct everything. In short, another agency of the Federal Government will have to do what the VA should have done over the last six years.

As I have discussed with you several previous times, the reason why the VA lost my paper-copy of my OPF from 1982 to 2002 is because I alleged that while I was the Chief of Surgery, Edward Hines, Jr. VAH, Maywood (Chicago’s tertiary VA hospital), IL, the VISN 12 Director called for my firing without cause 12 times as related to me during my deposition by the VA OIG HR specialist in the preparation of the: COMBINED ASSESSMENT PROGRAM REVIEW, EDWARD HINES, JR. VA HOSPITAL, HINES, IL, Report No. 99-00173-18, November 22, 1999. [Please note that the OIG presented to my Hines VAH office in October 1999 requesting documentation of the staffing of the Hines VAH OR and the documentation from page 43 through 61 of the CAP report #99-00173-18 was my work summary of the OR directed to the Director of the Edward Hines, Jr. VAH and my name is un-REDACTED on page 44.] Not only is a **Constructive Discharge** a prohibitive personnel practice, as alleged in “*section 45 Remarks*” in the SF 50 of 01/19/2002, illegal; but an EEOC Complaint was filed by me before the EEOC [EEOC No. 210-A3-6145X, Agency No. 200K-1886] and the MSPB resulting in the docketing by the U.S. Federal Court of Appeals for the Federal Circuit (USCAFC) in *Andrus v VA*, Case# 03-3162 with Oral Arguments on 3/3/2004. The U.S. Court of Appeals for the Federal Circuit failed to rule *per curiam*, but resultant to *Andrus v VA*, the phrase: **Level 3: Attending Not Present, immediately available** has been changed over the last 20 years in VHA Handbook 1400.1. The URL of the VHA Handbook was changed by the VA to 1400.01 so that the changes would be difficult to legally discover. Most of all, Attending Surgeon supervision of residents in VA Operating Rooms no longer permits or condones Attending Surgeons staffing VA OR cases in physical absentia (Ghost Surgery). ONCE again, Ghost Surgery **is no longer permitted nor condoned by the Veterans Health Administration.**

*Andrus v VA*, USCAFC Case# 03-3162, was initiated through the U.S. MSPB and the U.S. EEOC processes and when I returned to the VA in August 2016, I suffered a *de facto* demotion from a Physician Grade 15, Step 10 to a Physician Grade 15, Step 7 as “The rate of base pay is the rate payable for:” a specific Step (38 USC Sec. 7431, CH 74-Personnel, page 958). I allege that my *de facto* demotion in August 2016 (to Grade 15, Step 7) and all subsequent promotions to a Grade 15, Step 10 last August 2022, **are** wrong and resulted in an underpayment of my biweekly salary for the last 6+ years through the U.S. Department of Defense (DFAS) with full knowledge of individuals within the Veterans Health Administration of the U.S. Department of Veterans Affairs. I allege that listed above is consistent with a **8<sup>th</sup> possible EEOC discriminatory complaint** as I “...believe that I [*you*] have been discriminated against because of opposing a prohibited practice or participating in an equal employment opportunity matter...” Knowing that the VA pension is calculated by VA RSSO as the average of the highest 3-year continuous salaries, there is no way my pension can be calculated appropriately by VA RSSO until a legally U.S. Department of Veterans Affairs responsible / accountable **AUTHORITY** adjudicates my last 6 years salaries with a summation of legally appropriate Basic Pay and with my locality/market ADJ pay on my previous paychecks. Ms. Fairfield, since you conceded that you could not provide such adjudication, it would seem such a process is within the scope of our VA superiors, e.g.: the Under Secretary of Health, Veterans Health Administration, or the Secretary of the U.S. Department of Veterans Affairs. For the VA through the RSSO to dump

my “closed-out file on January 31, 2023” to DFAS and then OPM without resolution of my appropriate pension based on corrected salaries according to 38 U.S.C. Sec. 7431, CH. 74- Personnel, 958, is unconscionable, probably a violation of Title VII of the Civil Rights Act (Title VII), and dereliction of duty and consistent with obstruction of justice by all involved in the case of *Andrus v VA*, USCAFC Case# 03-3162, in the VA, DOJ, and OSC.

In summary, this is my understanding of the calculations for adjudication of a correct Gross Monthly Pension allocation:

1. Total number of years: In my case 25 years + ~1 year for accrued sick leave from 1982 to 2022: **SCD of 10/25/1996.**
2. Calculation of FERS Proration factor from Part-time and Full-time service:

From my calculated proration by the Edward Hines, Jr. VAH HR: “FERS Part-Time Employee Data” in 2001 and my Full-Time for the last 6 years from:

- A. (1) FERS service credit: 18 years 8 months 23 days (18.72 years)  
(2) FERS Part-time PRORATION Factor 81.0%
- B. (1) FERS service credit: 6 years 3 months and 27 days. (6.3 years)  
(2) FERS Full-time PRORATION Factor 100.0%

Total: 25 years 0 months 20 days. (~25.05 years)

$$X = \frac{(81.0\% / 18.72) + (100\% * 6.3)}{25.05} = 85.7\%$$

3. As my years of service are >20 years, one will multiple by 1.1
4. **Unfortunately, a VA authority should correct and adjudicate my salaries from August 2016 to the present based on correction of my Base salary in 2016 from the erroneous Grade 15, Step 7 to that which should have been in 2016 of Grade 15, Step 10 in continuation from 2002. Once the biweekly gross salaries from 2016 onward are recalculated regarding base salary, the last 3 years can be averaged and then:**

Averaged Adjusted Base Salary = Base salary + Location salary

Annual Pension Gross Salary should =  
Averaged Adjusted Base Salary \* proration of **85.7% \* 1.1**

Thus, Ms Fairfield, before the VA RSSO “closes my case” and transmits it to DFAS and OPM, **I plead with you that the above adjudication process and calculations should be completed by the VA before closing my case.** As the forms that are to be returned to you today by e-mail

were brought to my attention on January 9, 2023, I would assume that the “Drop Dead date” for the VA RSSO to close my **completed retirement package** is ~60 days from January 9, 2023 (~March 10, 2023). As per my previous submission methodology of September 24, 2022, all will be submitted through by U.S. Postal Service Priority Mail so it is trackable by the U.S. Postal Inspectors, and discoverable to the general U.S. public through a formal FOIA request of that which I will submit to the NIH NIAID case file #12276: this letter and its Appendices; a hard copy of Book 2, a hard copy of Book 3, and (to be sent later, a copy of Book 1) on a SDHC 16 GB card with all included so as to electronically searchable.

Ms Fairfield, I thank you very much for you past direction; but as you have informed me several times on the phone, you do not have the authority to adjudicate my Grade and Steps over the course of the last 6 years which, at present, are in error and thus an averaging over the highest three continuous years is impossible. As none of your supervisors have stepped up to the plate, I will continue to copy to the Office of General Counsel as per the directions of Michael Hogan, J.D. who previously was one of the members of the Office of VA General Counsel as the Designated Agency Ethics Officer (DAEO); to Secretary McDonough as he is the VA’s chief authority; and to President Biden as he is the Head of the Executive Branch of the Federal Government as designated by the U.S. Constitution.

Please review in detail this letter and ask of someone of authority in the U.S. Department of Veterans Affairs to adjudicate my requested review of the last six years to get my Grade and Steps corrected so an appropriate continuous salary of the last 3 consecutive years can be averaged in the calculation of my pension by VA RSSO?

Thank you,

Charles H. Andrus, M.D., F.A.C.S.  
Former Physician and Surgeon, Veterans Health Administration  
U.S. Department of Veterans Affairs  
Former Professor of Surgery, Department of Surgery Saint Louis University SOM  
Former Professor of Surgery, Department of Surgery, Loyola University (Chicago) SOM  
Interviewee for the position of Under Secretary for Health, Veterans Health Administration,  
U.S. Department of Veterans Affairs on December 10, 1999, along with:  
Thomas Bowen, M.D., F.A.C.S. (MG, retired),  
Thomas Garthwaite, M.D.,  
Robert Petzel, M.D., and  
Robert Roswell, M.D.  
Federal Whistle Blower in *Andrus v VA*, USCAFC Case #03-3162 with the concurrence and  
direction in 2001 of Micheal Staley, VA OIG, and James McManus, M.D., F.A.C.S., VHA  
Medical Inspector (U.S. Office of Special Counsel files: MA-00-1107 and DI- \_\_\_\_\_)



Cc:

Catherine Mitrano, J.D., and Michael R. Hogan, J.D.  
Office of General Counsel (26)  
Designated Agency Ethics Official (DAEO)  
810 Vermont Ave, N.W.  
Washington, D.C. 20420  
Phone: 202-360-2598  
**Re: NIH NIAID Case #12276**

Anthony S. Fauci, M.D.  
Director of the U.S. National Institute of Allergy and Infectious Diseases  
U.S. National Institutes of Health  
U.S. Department of Health & Human Services  
5601 Fishers Lane, MSC. 9806  
Bethesda, MD 20892-9806  
Phone: 301-496-5717 (last varified July 2020)  
FAX: 301-402-3573 (last varified July 2020)  
**Re: NIH NIAID Case #12276**

The Honorable Denis McDonough  
Secretary, U.S. Department of Veterans Affairs  
810 Vermont Ave, NW  
Washington, D.C. 20420  
[Denis.McDough@va.gov](mailto:Denis.McDough@va.gov)  
**Re: NIH NIAID Case #12276**

Abigail Carlson, M.D.  
Centers for Diseases Control/DDID/NCEZID/DHQP/OD  
1600 Clifton Road, Rm 3139  
Atlanta, GA. 30333  
404-718-8458  
[qqd6@cdc.gov](mailto:qqd6@cdc.gov)  
**Re: NIH NIAID Case #12276**

Kara Harris, MPH  
Section Chief for Controlled Correspondence and Public Inquires  
Legislative Affairs and Correspondence Management Branch  
Office of Communications and Government Relations  
U.S. National Institute of Allergy and Infectious Diseases  
U.S. National Institutes of Health  
U.S. Department of Health & Human Services  
5601 Fishers Lane, MSC. 9806, Room 6F30  
Bethesda, MD 20892-9806  
[Kara.Harris@nih.hhs.gov](mailto:Kara.Harris@nih.hhs.gov)  
Phone: 240-627-3693  
**Re: NIH NIAID Case #12276**

**Index of Appendices: Tonight January 29, 2023, I will attach the following Appendices to the transmitted e-mail.:**

Appendix A: Pamela and Charles Andrus, Marriage / License Certificate,  
July 27, 1985.

Appendix B: VA forms completed: SF 3107, SF 3107-1, SF 2818, W-4P  
(2023),  
and additionally:

Appendix C: U.S. Department of Veterans Affairs Commendations

Appendix D: Result of Audit of DFAS

**Due to oversize, my final submission of Books 2 and 3 converted into a pdf format with pageation (Which I sent on 9/24/2022 without page numbers) will be mailed by USPS over the next several days to VA RSSO, VA General Counsel and Secretary McDonough, the NIAID, etc.**

0.80 Attachment VI Email correspondence regarding Dr Hawley involment in VA-University affiliation e-mail pt 3pdf.pdf

## Re: Wikipedia lists Dr Hawley as both

From: Candrus600 (candrus600@aol.com)

To: kirbyj@wustl.edu

Cc: jasonkeune@gmail.com; montenegroga@slu.edu; eddy.hsueh@slucare.ssmhealth.com; hammillc@wustl.edu; candrus600@aol.com; denis.mcdonough@va.gov; qqd6@cdc.gov; kara.harris@nih.hhs.gov; jeffrey.stubbs@va.gov

Date: Monday, April 17, 2023 at 11:53 AM CDT

4/17/2023

NIH NIAID Case # 12276

Dear John:

Thank you so very much for looking into Dr. Hawley's status as a Fellow and Honorary Fellow of the American College of Surgeon and offering to bring the possible need of increased awareness to the ACS Board of Governors towards his importance regarding U.S. Army Medicine, the VA, the ACS, and, most of all, U.S. Medical School history as the University/VA affiliation helped expand and preserve our nation's Medicine and Surgery Residencies after WWII. Dr. Paul Hawley, with Dr. Magnusom, General Omar Bradley, and President Truman, was instrumental in PL-79-293 becoming a federal law on January 3, 1946,--the official establishment of the Departments of Medicine and Surgery of the Veterans Administration [now the Veterans Health Administration (VHA)].

Over the last nine months, I have had the opportunity to collate my thoughts, opinions, and writings, (and I am sure have provided amusement and consternation to many with my communications to those of the VA, FDA, NIH, etc.) regarding the unifying issue of concern of non-accountability in our society today especially regarding some physician/surgeon *de facto* incomplete dedication to duty towards every patient who presents--both within the VA and throughout Medicine in this country today. Francis Cardinal Gibbons, Catholic Archbishop of Baltimore and an advisor to 5 of the Presidents of the United States, over 100 years ago stated:

Reform must come from within, not from without. You cannot legislate for virtue.

Our society today has grossly failed to take heed of Cardinal Gibbons admonition thinking that we can legislate (or litigate) for good as we persist in our chronic denial towards many the contentious issues of our day. (See the attachment regarding a 1977 Letter to the Editor of the NEJM)

Dr. Hawley, Dr. Magnusom <https://news.feinberg.northwestern.edu/2021/02/25/celebrating-75-years-of-partnership-with-the-va/>, and Dr. Peustow would develop the template at the Edward Hines, Jr. VAH for the University/VA affiliation under PL-79-293 <https://weservedtoo.wordpress.com/2015/01/31/va-history-vas-department-of-medicine-and-surgery-established/> which established the Departments of Surgery and Medicine in the Veterans Administration (now the VHA) and on January 30, 1946, the VA would issue VA Policy Memorandum #2:

<https://web.archive.org/web/20100527201427/https://www.va.gov/oaa/Archive/PolicyMemo2.pdf> which would define and continues to define the VA-University Affiliation and demarcate and mandate the delineated responsibilities of the VA (patient care) and the Universities (education).

Attached are excerpts from Book 3 of my submissions to the VA, the FDA, the NIH, the CDC, and the President: *Dear Mr. President: ...to Care for Him Who Shall have Borne the Battle...* which I have been writing over the last twenty years. Attached is Chapter 3: The Dog Lab and two sections of Chapter 14: Discussion and Reflections.

John, thank you for presenting my concerns regarding the ACS acknowledgment of Dr. Hawley to the ACS Board of Governors. John, you and all the members of the ACS Committee regarding the regional candidates for ACS fellowship, it is my hope you will enjoy the attachments and share them *verbatim* with whomever you wish. It was and is an honor and a lot of fun participating annually (as it was yesterday) during our interviews of the ACS fellowship candidates for the eastern region of Missouri! Have a nice (and safe) summer.

Charlie

On Sunday, April 16, 2023 at 09:22:48 AM CDT, Kirby, John <kirbyj@wustl.edu> wrote:

A Fellow  
And an Honorary Fellow and  
They have an endowment/scholarship in his name

So hopefully we can get the College to confirm!  
Get [Outlook for iOS](#)

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The materials in this message are private and may contain Protected Healthcare Information or other information of a sensitive nature. If you are not the intended recipient, be advised that any unauthorized use, disclosure, copying or the taking of any action in reliance on the contents of this information is strictly prohibited. If you have received this email in error, please immediately notify the sender via telephone or return mail.



03 Chapter 3 The Dog Lab.pdf  
3.5MB



0.2 14 Chapter 14 Discussions and Reflections.pdf  
14.7MB



0.3 2006\_06\_18-Whatever\_you\_say\_Doc.pdf  
1.2MB



1977 Gilman lettter Yale University New Haven.pdf  
2.2MB

# The Dog Lab

# Chapter

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With many exotic new methods of conducting medical experiments including genetic testing and high technology in general, there remains a tried and true method of conducting the testing of innovative and potentially life-saving operations and procedures: the “dog lab.” For the research physician, physiologist, and surgeon alike, the laboratory specializing in the use of large animals, e.g.: dogs, is the place that physicians are able to test procedures before they are attempted on human beings. Organ transplantation, the development of procedures using endoscopic instruments, the use of lasers to perform surgery on the human eye and even surgery through the use of remote controlled robots all had their beginnings in *The Dog Lab*.

Human nature is not only averse to being exposed to the grittiness of life but it collectively wretches in response to such exposures. As demonstrated by Hurricane Katrina in August of 2005, life's realities are stark, stomach turning and piercing. And yet, much of modern life is littered with a grittiness that we cannot indulge in the focus of the mind's eye. Whether it is the irresolvable nature and sordidness of abortion, the unimaginable, brutal and inhumane nature of the Nazi experiments on human beings or research of the Tuskegee Study of African Americans with syphilis in which penicillin was deliberately withheld in an effort to better understand how the disease is spread and what its effects are on the human body, we have little stomach for such mind numbing sordidness. The slaughtering of animals for their fur and for the protein flesh they provide for our daily fare comes even closer to scarring placid images of the good life as it is lived on a daily basis.

The use of dogs as vehicles for surgeons to learn how to perform new operations strikes a similar chord. It is abrasive to human consciousness to think that dogs are expendable for such purposes, especially since so many fellow citizens treasure them as family members. Dog labs are decades old and by nature experimental. Given their unsung role in the development of American surgical procedures, it is no small wonder that legions of dogs have



## The Dog Lab

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been sacrificed on the altar of learning. As such, dog labs have come to represent a slaughter house of sorts, a place where the life of an animal is put at risk or sacrificed for the good of learning how to do something that would be of benefit to human kind. Due to the bloody and unsavory light in which the dog lab has come to be cast in the minds of surgical medicine, the dog lab has come to represent disparaging metaphor of sometime unconscionable practices.

Many years ago, the term “dog lab” was used as an instructional metaphor to then this newly named Veterans Administration (VA) hospital’s Chief of Surgery. A fellow senior surgeon offered the term as a description and an explanation of how some physicians have historically viewed the relationship between VA hospitals in general and the medical schools with which they affiliated over the course of the last sixty years. Thus, historically, the metaphor epitomizes the derogatory sentiments and allusions that some physicians and medical educators have made in the presence of their educational charges regarding the indigent and less-fortunate who are treated in our nation’s largest public hospital system.

The callous use of such a demeaning metaphor signals nothing less than a diminishment of human worth. In the verbal attitudes they express, all too often medical educators as role models convey implied values that impart heavy and unfortunately lasting meaning for their students. It is the method by which values both ill and good are transmitted over the course of generations. Even if untrue<sup>1</sup> initially and intended in reference to only one VA hospital, “The Dog Lab” is unimaginably derogatory to the U.S. Department of Veterans Affairs as an institution implying a substandard system of health care. Furthermore, it demeans and condemns those veterans who utilize the VA as their primary source of healthcare as somewhat less-than-human experimental subjects. And yet, it is the country’s veterans who exposed themselves in harms’ way to protect our way of life throughout our nation’s history. It is those same veterans who knowingly served their country not knowing when they were inducted and swore allegiance to the country whether they would be stateside for the duration of their military career or die in combat within six months of their induction. It is those very same veterans to whom Abraham Lincoln 140 years ago promised on our behalf: **“...to care for him who shall have borne the battle, and for his widow, and his orphan...”** It is those veterans--the short, the long and the tall, the drug addicted or alcoholic, homeless, chronically mentally ill and rife with unrelenting PTSD--to whom we owe our way of life. The manner in which they are treated in the healthcare system dedicated to them reflects on the very character of our country.

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<sup>1</sup>VA hospitals have been recognized in recent studies as providing an above average standard of healthcare quality. See *U.S. News & World Report*. July 18, 2005

## Chapter 3

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## **The Dog Lab**

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## Chapter 14: Discussions and Reflections

## XXXXXXChapter 14: Discussions and ReflectionsXXXXXX

One definition<sup>1</sup> of a scandal is: “A **publicized incident** that brings about **disgrace** or **offends the moral sensibilities of society**.” While many will find in *Dear Mr. President*: “...to care for him who shall have borne the battle...” elements that are offensive at many levels, the incidents involved have never risen to the level of a *Scandal*. How society views moral insensibilities and chooses to acknowledge that such insensibilities exist are really the core issues within *Dear Mr. President*: “...to care for him who shall have borne the battle...”. For an incident or series of incidents to become “scandalous” it is not merely that they are disgraceful or offend, but that they become known. Thus, *Dear Mr. President*: “...to care for him who shall have borne the battle...” was written solely to bring to public awareness that which exists that should offend the moral sensibilities of our society today.

The incidences that have been described in this book which should offend moral sensibilities are really isolated to individual patients even though collectively many have been at risk as was acknowledged indirectly in a recent publication.<sup>2</sup> (Over six years, 39,577 individuals underwent operation without the responsible attending surgeon-of-record present at the time of operation out of 610,660—6.48%) While 6.48% may be only one in fifteen patients, the practices of attending surgeon absenteeism were probably previously much higher and have been documented and known to the U.S. Department of Veterans Affairs and the affiliated universities for over thirty-five years.<sup>3,4</sup> As such, attending surgeon absenteeism was not only condoned and possibly encouraged, but also institutionalized over the years.<sup>5,6</sup>

Although most patients implicitly expect their “responsible attending” surgeon to be present in their individual operation, if the outcomes were equivalent, then one could possible argue that such practices were permissible as<sup>2</sup> “medical training is provided within a setting that allows an appropriate balance of supervision and independence without compromising outcomes, which makes VA hospitals a popular venue for physician trainees.” If one carefully peruses the recent pivotal report<sup>2</sup> from key individuals (the majority being prominent attending surgeons) within the U.S. Department of Veterans Affairs, the touted acclamation “to allay any concerns about supervision of residents in the ORs within VA hospitals” is contradicted by the very data presented. In the report, absolute outcomes which are those not subject to author interpretation were all statistically significantly higher (with p values of <0.001) in the group where the attending surgeon was never physically present during any part of the operation, [i.e.: 30-day mortality rate (2.66% versus 2.34%); return to OR (10.24% versus 8.19%); emergency cases (12.84% versus 6.79%)]. Unfortunately, not only have these outcomes been misrepresented by the aforementioned paper<sup>2</sup>, but this bias has seemingly been validated by a “Position Paper” in the same November 2005 issue of *The American Journal of Surgery*<sup>7</sup>: “A study just completed by Itani *et al* [7] shows that the former level 3 (attending supervision: attending immediately available, not in room) had not been associated with overall increased morbidity or mortality and, in fact, was protective.” [Although the 30-day morbidity rate<sup>2</sup> (*complication rate*), which represents all documented complications other than death, was lower (8.27% versus 10.47%), the identification of a morbidity is observer/recorder dependent and not an absolute outcome parameter—that, is to say, the identification and reporting of complications—short of deaths—are like “beauty” perceived “in the eye of the beholder.”]

In March 2006, I spoke by phone with Tim Flynn, M.D., F.A.C.S., Professor of Surgery and Dean for Graduate Medical Education at the University of Florida.<sup>8</sup> In the years 2007-2008, Tim will be the Chairman of the American Board of Surgery. In a very real sense, Tim has been one of the few surgeons in this country that has been willing to listen or even speak with me. After I presented my paper on mortality outcomes and the presence of attending surgeons at the time of operation<sup>9</sup> in Vancouver in 2003, it was he alone, at that time, who asked me to sit down with him and requested that I explain what had occurred that had stimulated me to pursue my focus on appropriate resident supervision.

Later, as conversations infrequently continued by phone, I raised the issue in March 2006 of the sentence in *American Journal of Surgery* position paper on patient care, surgical education, research, and faculty development: "A study just completed by Itani et al [7] shows that the former level 3 (attending supervision: attending immediately available, not in room) had not been associated with overall increased morbidity and mortality and, in fact, was protective." I heard kind of chuckle on the phone; and he did not correct me when I called such a statement incredibly stupid. He then advanced that the VA has changed. They are much more cognizant of resident supervision and the "compliance officers" are now monitoring attending physician presence at the VA (e.g. He gets a phone call from the compliance officer every time he has "core time" at the VA to confirm that he is physically present at the VA. (Core time is approximately 1/4<sup>th</sup> of the contractual weekly time agreed upon with the VA by the part-time attending physicians guaranteeing physical presence at specific times on the VA property.) He commented that recently the compliance officer confirmed on the phone's digital display that he was calling from an inside VA phone.) He then went on to state that indeed this type of surveillance had come about across the nation in the recent past.

I then made comment to the fact that we had fixed the problem without ever acknowledging that a problem existed. I stated that the mindset is still out there. I gave the example of the resident two years ago who in front of my fellow faculty members said that I, as an attending surgeon, had to let the junior residents make mistakes in the emergency room at night and on weekends so that they would not make the same mistakes when they went out into the real world. Tim concurred that such a statement was inappropriate. To my thought though, such a statement is condoned and permitted in our profession because we never admitted to any adverse outcomes publicly that resulted from inadequate attending surgeon supervision of residents in our public hospitals. In short, we have tacitly agreed to an ethic that is disparate in nature—the quality of the provision of medical care provided the individual patient is dependent on the social/economic class of the patient, the time of the day, and whether the attending surgeon feels like being present.

Tim concluded our conversation by stating that we must move ahead. It was his hope that during his next five years in academic medicine he will be able to advance the concept of graduated credentialing of surgery residents at the national level. With such a process, hopefully surgery residents will be appropriately supervised in their initial years by attending surgeons physically present in the operating room and also provided some independent operative experiences in their later years of training after operative competence demonstration and documentation (supervised by attending surgeons outside the operating room but immediately available in hospital). Although noble in the intention of advancing independent operative competence for the individual senior surgery resident within the structure of the formal residency, such a concept has the



inherent potential for abuse with regards to that which previously occurred in both the public and private sectors. Since the profession has never publicly acknowledged that about which is described in this text: *Dear Mr. President: "...to care for him who shall have borne the battle..."*, one can only anticipate that history will repeat itself in some form.

On March 4, 2004, the day after the hearing of the case *Andrus v VA* before the U.S. Court of Appeals for the Federal Circuit, accompanied by my wife, Pam, and my two oldest sons, we visited with the staffer of the U.S. House of Representatives Veterans Affairs committee with whom I had dealings for two years prior to that meeting. He brought us to an empty interview room in the House Office Building and began to explain to my wife, children, and myself his view of my involvement in what had transpired. He began by stating that having been in the military for many years, he had been instructed as to one form of bravery being defined by occurrences on the battlefield and that of a physical heroism. As he looked at my wife and children, he stated that Dr. Andrus has displayed the other form of bravery in which he had placed at risk his professional standing and financial solvency (and had lost) to stand by a principle. He stated that he doubted that I would ever be publicly acknowledged, but the system was slowly being pressured to change. By my providing information regarding resident supervision, I had helped provide the focus and direction for the Congress--and the VA was now being forced to change. It would not be a quick change--but it was now inevitable.

By that point in the conversation, my family was in tears. I was being told I had had my Pyrrhic victory and I should take consolation. Unfortunately, I may have succeeded in being part of the impetus for creating a new bureaucracy with compliance officers who would monitor attending surgeon presence at the VA. I had not affected the *de facto* mindset of the profession that "See one, do one"...under attending surgeon supervision was expected, but then "teach one"...without attending surgeon presence was still permissible in individual cases. James Cardinal Gibbons is quoted to have said a century ago: "Reform must come from within, not from without. You cannot legislate for virtue."

Although I may have slightly diminished the outward verbalization and expression of the Dog Lab mindset, it is doubtful many hearts were ever changed. Too often in our society today, we have been witnesses to individuals who have "gotten away with it." We have equated *de facto* that which is undiscoverable or legally minimized as not morally or ethically significant. It is easier to argue ethically in the abstract than to address that which is tangible—real patients who were provided their medical care disparately to their individual potential detriment. The Congressional staffer calling my actions and my positional stance brave may be right—but I don't feel like a hero. To have followed through in what I have attempted passionately to accomplish has, in my opinion, required tenacity of will to continue when others have chided me for my appeals and ignored and diminished my message; blind-resolve to purpose bordering on overzealous commitment; and, most of all, a tremendous amount of personal naiveté. In our present almost-narcissistic societal mindset, just so long as our actions don't directly affect us and are not anticipated to haunt us individually, there is little impetus today to champion "the just cause." When a physician is able to justify the necessity of adverse outcomes or minimize clinical errors suffered by the individual patient in the education of physicians-in-training, I think we should take pause for this is in contradistinction to that which has its origins 2,500 years ago: "do no harm." Obviously, no physician would

wish an adverse outcome to befall a loved-one for education sake. The pledge I expressed in 1990 at my initiation into the fellowship of the American College of Surgeons should be a universal axiom: "...Moreover, I promise to deal with each patient as I would wish to be dealt with were I in his position...."

By this point, the reader probably is questioning why the incidences and potential scandals that are related in *Dear Mr. President*: "...to care for him who shall have borne the battle..." have never risen to the consciousness of the American public. As the previous chapters have related, the issues have been known to many individuals and groups within the United States government, academia, the media, and religious organizations. Unfortunately, today—and probably throughout human existence—the risk of publicizing a controversy is always tempered by individual and institutional self-preservation agendas. Indeed, while individuals (e.g.: Anthony J. Principi, former Secretary of the U.S. Department of Veterans Affairs) and even institutions (e.g.: the AMA Committee on Ethical and Judicial Affairs) in private communications have been shocked, dismayed, or outraged and encouraging in my pursuit of correction of the problems in the supervision of surgery residents, no one has publicly acknowledged the problems. Why have none voiced these issues publicly?

One might look at the response to any significant social controversy displayed by individuals, organizations, and the government as a continuum much like a Gaussian distribution (a bell-shaped curve). The vast majority of individuals will be buffeted between those who are passionate in their response versus those that despair. With the progression of time, such a distribution is not static, though, for as the time-line of the controversy progresses, the involved entities may vacillate from both extremes--from the periods of elation to the depths of depression--but most will return to a central position of the majority.

In any human controversy, all that can be anticipated is possible resolution. Like the human response distribution to any controversy, the adjective descriptors of the resolution of such social conflicts are concomitantly variable and disparate: ethical, good, acceptable, unacceptable, criminal, unethical, immoral, morally-reprehensible, crimes against humanity, etc. In the resolution of any human ethical dilemma, one can only pray for a just and fair conclusion. After the Cuban missile crises of 1962 when our world had been on the brink of nuclear annihilation, President John Fitzgerald Kennedy stated before the graduates of the American University, June 10, 1963:

...What kind of peace do we seek?...Not the peace of the grave or the security of the slave. I am talking about genuine peace, the kind of peace that makes life on earth worth living, the kind that enables men and nations to grow and to hope and to build a better life for their children—not merely peace for Americans but peace for all men and women—not merely peace in our time but peace for all times....For, in the final analysis, our most basic common link is that we all inhabit this small planet. We all breathe the same air. We all cherish our children's future. And we are all mortal.

Medicine has been called one of the noblest of professions. Throughout the ages the Western World has professed the adherence to the principles of the Hippocratic Oath. As of late, the significance and adherence to many of the principals of the Oath have been diminished and dismissed. In the last century we have witnessed the complete antithesis

to adherence to the Oath personified in the Nazi medical experiments of World War II. Elie Wiesel, Professor of Religion and Philosophy at Boston University, Nobel Peace Prize recipient in 1986, and survivor of the Buchenwald concentration camp on April 14, 2005 published *Without Conscience* in *The New England Journal of Medicine*:

...During the period of the past century that I call Night, medicine was practiced in certain places not to heal but to harm, not to fight off death but to serve it. In the conflict between Good and Evil during the Second World War, the infamous Nazi doctors played a crucial role. They preceded the torturers and assassins in the science of organized cruelty that we call the Holocaust. There is a Talmudic adage, quite disturbing, that applies to them: *Tov she-barofim le-gehinom*—"The best doctors are destined for hell." The Nazi doctors made hell.

Inspired by Nazi ideology and implemented by its apostles, eugenics and euthanasia in the late 1930s and early 1940s served no social necessity and had no scientific justification. Like a poison, they ultimately contaminated all intellectual activity in Germany. But the doctors were the precursors. How can we explain their betrayal? What made them forget or eclipse the **Hippocratic Oath**? What gagged their conscience? What happened to their humanity?

...In October 1939, several weeks after the beginning of hostilities, Hitler gave the first order concerning the *Gnadentod*, or "charitable death." On the 15<sup>th</sup> of that month, gas was used for the first time to kill "patients" in Poznań, Poland. But similar centers had already been created in Germany three years earlier. Now, psychiatrists and other doctors collaborated in a professional atmosphere exemplary for its camaraderie and efficiency. In less than two years, 70,000 sick people disappeared into the gas chambers. The *Gnadentod* program was going so well that the head of the Wehrmacht Hospital psychiatric ward, Professor Wurth, worried, "With all the mentally ill being eliminated, who will want to pursue studies in the burgeoning field of psychiatry?" The program was interrupted only when the bishop of Münster, Clemens August Graf von Galen, had the courage to denounce it from his cathedral's pulpit; protest, in other words, came not from the medical profession, but from the church. Finally, public opinion was moved; too many German families were directly affected.

Like the fanatical German theorists, Nazi doctors did their work without any crisis of conscience. They were convinced that by helping Hitler to realize his ambitions, they were contributing to the salvation of humanity. The eminent Nazi doctor responsible for "ethical" questions, Rudolf Ramm, did not hesitate to declare that "only an honest and moral person may become a good doctor."

The original movie, *The Exorcist*, was probably one of the most horrifying movies ever produced by Hollywood. It portrayed nothing less than the **devil incarnate**. Unbeknown to most Americans, though, the storyline is based on historically recorded occurrences transcribed by Raymond Bishop, S.J. that transpired in St. Louis in the Spring of 1949. Many years later, through Thomas Allen's literary work, *Possessed*, the 26-page diary of Father Bishop related the story for public review of the reluctant exorcist, William Bowdern, S.J., the Pastor of St. Francis Xavier Church of St. Louis University. By the time I was a medical student and resident at St. Louis University, Father Bowdern was in retirement from St. Francis Xavier parish. As I now contemplate the collation and completion of *Dear Mr. President*: "...to care for him who shall have borne the battle..." , I marvel at how even minor transgressions and omissions on our part can affect adversely our fellow man.



Whether one is an atheist or believes in God or the devil, evil is always with us. President Abraham Lincoln was fictionally attributed in the 1960 Disney movie *Polyanna* to have stated: “When you look for the bad in mankind expecting to find, you surely will.” Unfortunately, today we seldom look to see if our actions have wronged others for we have found that the denial of the evil we have incurred on others by our commissions or omissions can easily be discounted with arguments and other justifications. Our personal shortcomings and dereliction to our responsibilities can all too often be diminished, transferred to others, or wrongly alleged of the very institutions or individuals we have harmed. That is the evil incarnate that is pervasive in our society today. Truly, it is not just the fact that ghost and itinerant surgeries were practiced by many physicians and condoned by the universities and the VA that makes this story so tragic, but at every turn responsible individuals felt it justifiable to ignore what had become for some the *status quo*.

In stark contrast to that which I have related above and throughout this collection, I attended recently with our five boys and my wife the funeral of our children’s former pediatrician, Austin “Roger” Sharp, M.D., who was a graduate of the University of Notre Dame and later St. Louis University School of Medicine. Although Dr. Sharp’s son stated that his father never wished to be eulogized, his son stated that some honor was due his father whom he had observed was always there for his patients and who was also deeply committed to his family—reveling in all the facets of family life including outings and get-togethers even in the face of adversity (e.g., as when the old station wagon full of the family’s children became disabled from vapor-lock during their vacation trek across the Kansas expanse). Lovingly, Dr. Sharp’s son related that he remembered his father’s dedication to the patients’ families—on nights, on the weekends, and every other inconvenient time.

When in June 1990 our three-year-old son, Charlie (primary author of Chapter 4 of this book) had just survived acute pancreatitis and subsequent hemorrhagic shock induced by the anticonvulsant valproic acid and was still experiencing 200 myoclonic seizures per day, Dr. Sharp had asserted primacy in our son’s care by calling a meeting of the specialists. As the pediatric specialists (neurologist and gastroenterologist) discussed the treatment options, Dr. Sharp took my wife and myself aside and stated: “I haven’t a clue as to what is really going on with Charlie, but neither do they!” While it would be a decade later in a review article in *The New England Journal of Medicine* in which the constellation of mitochondrial encephalomyopathies would be described for the rank-and-file physician, Dr. Sharp’s sincere personal assurance of his medical ignorance was more reassuring to my wife and myself than any platitudes, theories, or professional pontifications that had been or would be advanced regarding our son’s condition. Indeed, the presence and concern of the attending physician that is visible to the individual patient represents the physician’s personal validation to his patient and his personal allegiance to the intent of *primum non nocere* and the Hippocratic Oath.

Like Austin Sharp, M.D., Thomas A. Dooley, M.D., was also a graduate of the University of Notre Dame and St. Louis University School of Medicine. Dr. Dooley is known in history for specifically his establishment of rural clinics in Southeast Asia at the conclusion of the French Indochina War and more generally as a humanitarian of whom Albert Schweitzer, M.D. complimented with the paraphrase of Kahlil Gibran: “The significance of a man, Dr. Tom, is not in what he attains, but rather in what he longs to attain.” Like Dr. Sharp, though, it was Thomas Dooley’s concern for every patient that

makes his story so compelling. At the patient level, is not such commitment the outward expression of *primum non nocere*?

Even those who privately responded with acknowledgement of the aberrancies in attending surgeon supervision of surgery residents that transpired over the last half of century have never spoken publicly. Thus, the addenda to *Dear Mr. President: "...to care for him who shall have borne the battle..."* are, in part, really a collage of primary sources regarding the response to my pleas for review and self-reflection. Individually, the various correspondences may amount to little, while the collection may be a powerful commentary.

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As a society and as institutions we have in the last decade hung our hats—so to speak—on quality assurance, continuous quality improvement, etc.<sup>1</sup> We have developed systems of review and methodologies to identify errors of miniscule proportions, and yet that which has been described in *Dear Mr. President: "...to care for him who shall have borne the battle..."* has essentially been ignored at every level in Academia, Medicine, and the U.S. Government. We, as a society today, have seemingly forgotten that which must be reiterated: "Reform must come from within, not from without. You cannot legislate for virtue."<sup>2</sup>

President Harry S Truman has been reported to have had on his Oval Office desk a sign with the expression: "The buck stops here."<sup>3</sup> In the final analysis, it was that admonition that drove my persistence in my attempts to raise the issues in *Dear Mr. President: "...to care for him who shall have borne the battle..."* before the Office of the Counsel to the President and the President of the United States of America. In his farewell address to the American people in January 1953, President Truman advised<sup>3</sup>:

The President—whoever he is—has to decide. He can't pass the buck to anybody. No one else can do the deciding for him. That's his job.

Let it be understood by every reader of *Dear Mr. President: "...to care for him who shall have borne the battle..."* that this anthology was not collated as a personal commentary on the degree of responsiveness of either the Clinton or Bush administrations to the issues raised. Rather, I have written this narrative to point out several significant moral axioms pertinent to our American society today and humanity throughout all times.

We should be ashamed when we ignore as individuals, as institutions, or as a society as a whole, our nation's promised adherence to protect and not deny the individual's rights<sup>4</sup>:

We hold these truths to be self-evident, that all men are created equal, that they are endowed by their Creator with certain unalienable Rights, that among these are Life, Liberty and the pursuit of Happiness.—That to secure these rights, Governments are instituted among Men, deriving their just powers from the consent of the governed.—that whenever any Form of Government becomes destructive of these ends, it is the Right of the People to alter or to abolish it, and to institute new Government, laying its foundation on such principles and organizing its powers in such form, as to them shall seem most likely to effect their Safety and Happiness. Prudence, indeed, will dictate that Governments long established should not be changed for light and transient causes; and



accordingly all experience hath sewn, that mankind are more disposed to suffer, while evils are sufferable, than to right themselves by abolishing the forms to which they are accustomed. But when a long train of abuses and usurpations, pursuing invariably the same Object evinces a design to reduce them under absolute Despotism, it is their right, it is their duty, to throw off such Government, and to provide new Guards for their future security.

Demonstrable throughout our previous national imperfect history and aberrancies in our nation's universal protection of human rights (e.g.: slavery, the American-Japanese internment during World War II, Jim Crow laws, child labor exploitation, separate but equal, etc.), *Dear Mr. President*: "...to care for him who shall have borne the battle..." has attempted to outline the imperfectness and lack of adherence to that which we, as a people, profess.

It is anticipated that with the publication of *Dear Mr. President*: "...to care for him who shall have borne the battle..." , the Veterans Health Administration of the U.S. Department of Veterans Affairs will attempt to diminish the significance of the narration. Attributable to the ongoing investigations and reports of the VA Office of the Inspector General<sup>5-7</sup> over the last three years, individual attending surgeon and physician supervisory practices have been scrutinized and actively influenced by increased oversight by the Veterans Health Administration. While such increased scrutiny was indicated, some physicians have found such oversight burdensome or insulting as they now are being required to "punch a clock." Unfortunately, since neither the physicians nor the affiliated universities have ever publicly admitted to the issues outlined in *Dear Mr. President*: "...to care for him who shall have borne the battle..." , it is unlikely that there will occur any fundamental change in physician mindset, attitudes towards the public hospital patients, or regard for the VA. Although that which is within *Dear Mr. President*: "...to care for him who shall have borne the battle..." is, at present, obscurely within the public domain<sup>8-11</sup> and being addressed and redressed as mentioned above, for most physicians the increased scrutiny and implemented documentation methodologies are annoying, bureaucratic, and non-sensible at best. By implementing correction without acknowledging the problems, we have failed to remember that: "Those who cannot remember the past are condemned to repeat it."<sup>12</sup>

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After one has perused the following narrative, I ask of the reader to take a moment for reflection. Ask what it will take to affect a change in the ingrained mindset regarding the disparate provision of medical care to individuals in our society based on economic or societal position. Can disparate attending physician attention to the individual patient be justified for the greater good of the educational experience? What will it take for society to address the issues raised in *Dear Mr. President*: "...to care for him who shall have borne the battle..."

This book asks of the physician a rededication to the principles and intent each individual physician has expressed in their swearing of the Hippocratic Oath. What will it take to affect such a change? How can these issues be brought to public awareness? Four hundred years ago, Shakespeare through Hamlet verbalized: "The play's the thing wherein I'll catch the conscience of the king." Hopefully, this book will be "the play" to catch the consciousness of physicians. There are still many role models out there like Austin Sharp, M.D., Thomas Dooley, M.D., and Albert Schweitzer, M.D. who place equal value and attentiveness on all their patients. As he was beatified in the process of determining sainthood on October 9, 2005 by Pope Benedict XVI, will it instead take a saintly individual like Cardinal Clemens August Graf von Galen mentioned in *Without Conscience* to affect a lasting change?

Unfortunately, the inherent evil to diminish the human worth of another individual by disparate treatment is all-too-easy and always present. Although many of our society's inequities were institutionalized during the founding of our country (e.g. slavery), it was the just philosophy that "all men are created equal" that should be the beacon for all—but especially the noble profession of medicine. To address the specific issues of physician absenteeism and the disparate provision of medical care to any member of our society, though, it is Francis W. Peabody, M.D.'s insightful admonition of seventy-five years ago that must become ingrained in the minds of all physicians to the end of time: "...for the secret in the care of the patient is in caring for the patient..."

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## Whatever you say, Doc

While *Dear Mr. President*: "...to care for him who shall have borne the battle..." was written to emphasize that we as the American people are, and should be, indebted to all American Veterans and must fulfill our appreciation towards them in abiding by our promises to them, I wish to thank many of the veterans in my life who personally influenced what has been written. As I was a physician and surgeon in the VA for eighteen years, I first must emphasize that in the aggregate the American veteran patient has always demonstrated graciousness and courage no matter what the circumstances. There were too many times in my life as a VA surgeon where I was obligated to admit Medicine's and my shortcomings to the veteran and his or her family when explaining the terminality of their illnesses or advocating for amputation to save a life. In the vast majority of cases, though, their seemingly universal and natural response to my diagnostic assessment and therapeutic suggestions was always: "Whatever you say, Doc." In that simple statement, the veteran patients expressed to me their life-long affiliation as "citizen soldiers" with a sense of dignity in the face of adversity and with a sense of honor and duty to their country transcending their personal needs.

As Americans, we all have a perpetual indebtedness to our veterans that is merited and deserving. That is the fundamental meaning of President Abraham Lincoln's promise<sup>1</sup>: "...to care for him who shall have borne the battle..." With approximately 25 million veterans alive today (and an annual attrition rate of approximately 690,000)<sup>2</sup>, we can all find some commonality as we are all relatives or acquaintances with presently living veterans or those that have died in the past. We probably all have individual veterans of whom we can relate personal stories and wish to express our gratitude. Professionally, as a physician and surgeon, I am extremely grateful to all the veterans throughout the years through whom in my personal interactions with them I developed a better appreciation of specific medical and surgical diseases and a better understanding of the human condition. I observed, assisted, and performed many of my first operations in the operating rooms of the VA. In relating their personal medical histories, I vicariously experienced through the veterans' memories the clinical descriptions of malnutrition states such as "wet" beri-beri as described by a former serviceman confined to a Japanese prison-of-war camp during WWII.<sup>3</sup> Forty years after-the-battle but with the recent institution in the patient of the anticoagulant coumadin, I treated a patient with ruptured pseudoaneurysms from shrapnel that was still present. I thank each and every veteran for aiding in my medical education.

I am most grateful, though, to those that lived and personally demonstrated on a daily basis the ethical principles that they had nurtured while in the service of their country. In this seemingly narcissistic era of reported individual and corporate scandals and greed, it may be difficult for "us" civilians to comprehend truly the motivations of honor, duty, and *esprit de cour*. Yet each of us has their personal memories of those veterans that have throughout their lives epitomized that of which I write. The following are those that I wish to acknowledge individually and thank personally for their example and influence on my life:

After graduating with a degree in chemistry from St. Mary's College<sup>4</sup> in Moraga, California, my father, Charles Hiram Andrus, Jr., served as an enlisted man (corporal) in the Chemical Warfare division of the U.S. Army during the latter half of World War II. While with Chemical Warfare, he was assigned to such places as Camp Sibert, Alabama; Edgewood Arsenal, Maryland; and San Jose Island, Panama Canal Zone.<sup>5</sup> (San Jose Island is one of the Pearl Islands best known to many Americans today through the CBS television reality series: *Survivor*<sup>6</sup>) After World War II, my father worked as a chemist for Golden State Dairies (which would later become part of Foremost Dairies) where he met my mother. From roughly 1948 to 1985, he worked as an analytic chemist for California Packing Corporation (CPC: the company name was changed in the 1960s to that of the name on the label of CPC's can goods: *Del Monte*) in DDT analysis; nutritionally labeling (prior to the USDA mandate on all food products); and, prior to his retirement, wastewater chemical analysis of cannery waste as was mandated by municipal sewage systems and advised by the US EPA.

On October 25, 1944 during the Battle of the Leyte Gulf, my uncle, Albert Roth, was a young seaman on the only aircraft carrier in U.S. history sunk by enemy surface fire, the U.S.S. Gambier Bay.<sup>7</sup> Surviving in shark infested waters for over two days, he was sent for R&R to Hollister, California where he met my aunt, they would marry, and they subsequently had two sons: Randy and Barry. After WWII, on the GI bill, my uncle would become a civil engineer who would later work for engineering firms involved in the design and construction of salmon ladders for the hydroelectric plants and hardened silos for ICBMs of the American northwest. In retirement, he continued his life long avocation of woodworking. Using plans obtained from the Naval Archives with his son, Barry, he constructed a scale model of the U.S.S. Gambier Bay which is today on public display<sup>8</sup> on the U.S.S. Hornet<sup>9</sup> at the Alameda Naval Air Station in San Francisco Bay. Randy, a Professor of U.S. History at Ohio State University, and his wife, Allison, an editor for literary journals, were my coauthors of the article on safety and quality assurance in the VA: "*To Err is Human*": *Uniformly reporting medical errors and near misses, a naive, costly, and misdirected goal*.<sup>10</sup> At the request of the staff of the Joseph and Rose Kennedy Institute of Ethics Library, that article is part of the collection at Georgetown University of the National Reference Center for Bioethics Literature of the U.S. National Library of Medicine.<sup>11</sup>

Like all the veterans on this personal acknowledgement list, Lt. Colonel Thomas Lee Crull, (ret), distinguished himself in countless ways both in military service and in civilian life. As my best friend (and girl friend) in college, Colonel Crull's daughter, Sandy, always spoke of her father with loving admiration. He had been a combat pilot during World War II, the Korean War, and the Vietnam War. For me, he was always a very personable, energetic individual, who after his retirement from the US Air Force decided to return to school and graduated from college with degrees in business in the 1970s.

Although his family and he spoke little of the specifics of his military career, with the declassification of documents in recent years and the globalization of the Internet, he will always be viewed in history as one of the many Air Force servicemen instrumental in our vigilance during the Cold War.<sup>12-16</sup> Most Americans who were alive in the late 1950s

and early 1960s will remember one of the types of planes he flew during his career—the U-2:

On Sept. 24, 1959, Thomas L. Crull was flying a newly arrived U-2C, Article 360, on a local flight, heading back to Atsugi after setting an altitude record. As the U-2's fuel ran out—forcing Crull to make a dead-stick, wheels-up landing at the Fujisawa glider strip, 10 miles from Atsugi. Crull emerged unhurt, but his airplane overran the runways and slid onto the grass.

Letting the airplane simply sit there unguarded was not an option. A short time later several security personnel, apparently wearing loud Hawaiian shirts and packing large revolvers, showed up and began to order the growing crowd at gunpoint to stand away from the secret aircraft. The tactic prove counterproductive as it only led to extensive publicity about the crash landing. Eventually, the airplane would be packed off to the US, repaired, and returned to service with Det. B in Turkey.

While Colonel Crull's flight on September 24, 1959 was at the time of intense local Japanese interest, it would be the final flight of Article 360 that would catch the eye of the world. After being repaired at the Lockheed Martin Skunk Works<sup>15</sup> and reassigned to Turkey, on May 1, 1960, the U-2C airplane known as Article 360 would be brought down by surface-to-air missiles over Sverdlovsk, USSR. Piloted by Francis Gary Powers, this U-2 downing would become an international incident of intense focus magnifying the frictions of the Cold War.

During the trials and tribulations of the incidents related in this book, there are three non-physician veterans to whom I am personally indebted: Edward Nagorski, Phil Mazur, and Leonard Sistik. Mr. Nagorski as a young man had been wounded and taken prisoner during the Battle of the Bulge. Like the other veterans on my list, it was not his battle heroism that distinguished him for me, but rather all the pleasant discussions, advice, and advocacy on my behalf that he and his wife would provide to me over my years as the Chief of Surgery, Edward Hines, Jr. VAH.

Mr. Mazur is indeed one of a kind-- the Veterans' veteran. With untiring resolve and purpose, he has vocalized veteran concerns before county advisory boards, Congressmen, and VA administrators.<sup>16,17</sup> Yet he has personally advocated to this former Chief of Surgery on behalf of individual fellow veterans in need of attention and, without acknowledgement, transported wheelchair-bound veterans to Christmas services.

In February 2002, at the direction and request of The Honorable Lane Evans, ranking Democrat on the U.S. House of Representatives Veterans Affairs Committee, I received a call from Mr. Leonard A. Sistik, Jr., a U.S. Air Force veteran and Democratic Staff Director<sup>18</sup>, Subcommittee on Oversight and Investigations, Veterans Affairs Committee, U.S. House of Representatives. Of the approximately 536 letters of advocacy that had been sent to each member of Congress and the President in December 2001, only Congressman Evans, Illinois 17<sup>th</sup> Congressional District, (through Mr. Sistik) ever acknowledged receipt of my letter of advocacy. He requested of Mr. Sistik that Mr. Sistik contact me and request a summary of my concerns. Even though the response to that request was completely factual and all-important, what Mr. Sistik received from me was a deluge of paper, a passionate stream-of-consciousness, and a hodge-podge of correspondence and documentation. In April 2002, while in attendance at the

Association for Surgical Education meeting in Baltimore, Maryland, I decided to take the train to Washington, D.C. and meet Mr. Sistek for the first time. Inconsistent with my continence and facial features being those of a M.A.S.H. company clerk, Mr. Sistek smiled at me and stated: "You sure don't look like the vindictive SOB that the VA has made you out to be." It quickly became clear to me that "someone" had provided *ad hominum* dissertations about me to the staff and some members of Congress. Over the years, Mr. Sistek continued to listen and read my stream-of-consciousness e-mail correspondence—(I'm sure to the point of eye-strain); but he always calmly and cordially advised and counseled. As was mentioned in this book, on March 4, 2004, with my wife and two oldest sons in tears, he thanked me for my submissions while advancing the Committee's personal gratitude—I will always be indebted to him for this personal act of kindness.

While this book might possibly confirm for many the prejudices, biases, and unsubstantiated generalizations that all physicians and surgeons will take advantage of the situation, I will list below some of the physicians (all who are American veterans) that have been instrumental in my life who have demonstrated their commitment to all their patients individually, have ethically taught by their daily caring for patients, and have personally demonstrated: "...to care for him who shall have borne the battle...": Frank E. Johnson, M.D., F.A.C.S.<sup>19</sup>, Chief of Surgery, St. Louis VAMC and Professor of Surgery, St. Louis University; Terence P. Wade, M.D., F.A.C.S.<sup>20</sup>, (Col., U.S. Air Force Reserve, ret.), former surgery faculty at the St. Louis VAMC and former Associate Professor of Surgery, St. Louis University; Vallee L. Willman, M.D., F.A.C.S., Professor and Chairman, *emeritus*, Department of Surgery, St. Louis University<sup>21</sup>; Frank Folk, M.D., F.A.C.S., former Assistant Chief of Surgery, Edward Hines, Jr. VAH (for >22 years) and Professor of Surgery, Loyola University, Chicago<sup>22,23</sup>; and Enrique Mendez, M.D., M.G., U.S. Army, (ret)<sup>24</sup>, former Assistant Secretary of Defense (Health Affairs) and former President and Dean, Ponce de Leon School of Medicine, Puerto Rico.

All the aforementioned veterans were personally influential throughout my life in their daily demonstration of ethical behavior. Through my affiliations with St. Louis University and the U.S. Department of Veterans Affairs, there are four American veterans who were physicians of whom I consider my personal "historical" mentors regarding "adherence to duty": William Beaumont, M.D.<sup>25</sup>, Paul R. Hawley, M.D., F.A.C.S. (hon.), MG, USA, (ret)<sup>26,27</sup>, Thomas Dooley, M.D.<sup>28,29</sup>, and Vice Admiral Joel T. Boone, M.D.<sup>30-33</sup>

***Add discussion regarding Deliver Us From Evil<sup>34</sup> description and the article by Boone defending the VA before the AMA<sup>35</sup>***

As I have contemplated a "thank you" in the aggregate to all the aforementioned veterans (and all American Veterans) who have touched my life personally and have affected my viewpoint as a physician and surgeon throughout my life, I must emphasize their commonality. The majority are "fathers" and I thus find it most fitting that I am

composing part of this portion of *Dear Mr. President*: "...to care for him who shall have borne the battle..." on Father's Day, 2006. Like all "fathers" these men have demonstrated their loving nurturing of their "children"—whether they are their biological offspring or the notions and dreams for a better future for all of us. All these men in their daily lives demonstrated ethical behavior and their sense of honor and of duty to their country.

When we diminish their significance by our indifference and our inattentiveness to them as individuals, we are their prodigal<sup>36</sup> children. It is not enough for us to "honor" our veterans on every Memorial Day and Veterans Day only—we are obligated to honor them forever as was promised and immortalized by President Lincoln.<sup>1</sup> While Mr. Lincoln's Second Inaugural Address<sup>1</sup> is engraved on the north wall of the Lincoln Memorial, *The Gettysburg Address*<sup>37</sup> which speaks in a more general sense of our inadequacies to honor our veterans—both living and dead—is engraved on the south wall:

... We have come to dedicate a portion of it, as a final resting place for those who died here, that the nation might live. This we may, in all propriety do. But, in a larger sense, we can not dedicate—we can not consecrate—we can not hallow, this ground—The brave men, living and dead, who struggled here, have hallowed it, far above our poor power to add or detract. The world will little note, nor long remember what we say here; while it can never forget what they did here....

Throughout our history as a nation, all our veterans have protected that which we hold dear. In final tribute and thanks to our Veterans (both male and female, living and dead), I will conclude with a possible explanation<sup>38</sup> as to why our "fathers"—the "American Veterans" have placed themselves in harms way for all of us and are most deserving of our perpetual attentiveness:

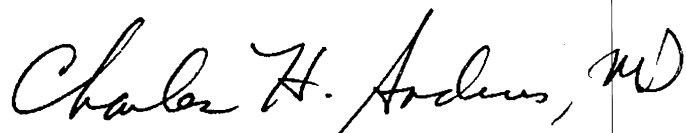
What kind of peace do we seek? I'm talking about genuine peace—the kind of peace that makes life worth living. Not merely peace in our time but peace in all times. Our problems are man made—therefore, they can be solved by man. For in the final analysis:

Our most basic common link is that we all inhabit this small planet, we all breathe the same air, we all cherish our children's future, and we are all mortal.

--President John Fitzgerald Kennedy

It has indeed been my honor, my privilege, and my duty to have related the stories contained within: *Dear Mr. President*: "...to care for him who shall have borne the battle..."

Respectfully yours,



Charles H. Andrus, M.D., F.A.C.S.  
Former Chief, Surgical Services  
Edward Hines, Jr. VAH, Chicago, IL



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<sup>37</sup>Lincoln A. Gettysburg Address, Gettysburg, PA, November 19, 1863. Our Documents - Gettysburg Address (1863)

<http://www.ourdocuments.gov/doc.php?doc=36> (Last accessed on June 18, 2006)

<sup>38</sup>Kennedy JF. Commencement Address at American University – John F. Kennedy Presidential Library & Museum.

<http://www.jfklibrary.org/Historical+Resources/Archives/Reference+Desk/Speeches/JFK/003POF03AmericanUniversity06101963.htm> (Last accessed on June 18, 2003) [The referenced quote is actually a paraphrase and condensation of President Kennedy's speech which concludes the movie: *Thirteen Days* Donaldson R, director. Infinifilm, 2001. <http://www.amazon.com/gp/product/B00005J760/002-5717398-2668848?v=glance&n=130> (Last accessed on June 18, 2006)]





Dear Mr. Secretary and Mr. President:

Below what follows is a Letter to the Editor in March of 1977 of *The New England Journal of Medicine*:

Lynch EJ: **A CASE OF CHRONIC DENIAL.** *N Engl J Med* 1977; 296: 638. DOI: 10.1056/NEJM197703172961126.

<https://www.nejm.org/doi/full/10.1056/NEJM197703172961126>

There was never any official response or comment to the aforementioned letter in the medical literature that is known to Dr. Lynch (the author) or myself. The ONLY response was a handwritten letter that follows from Alfred Gilman, Ph.D of Yale University--an elaboration by Dr. Gilman on **CHRONIC DENIAL SYNDROME** which is subliminal, pervasive, and all-encompassing in every walk of life of our society today and has become *de facto* a methodology and justification that we will **NEVER** admit that we are wrong -- **For We are Never Wrong!** Alfred Gilman, PhD with Louis S.

Goodman,

M.A., M.D., D.Sc. (Hon.) of: *The Pharmacological Basis of Therapeutics*, 5th Edition, Goodman LS, Gilman A, editors and the associate editors: Gilman AG, (the senior Dr. Gilman's son who awarded the Nobel Prize in Medicine or Physiology for his discovery of G-receptors), Koelle GB, associate editors. (New York: MacMillan Publishing Co., Inc, 1975; Toronto: Collier MacMillan Canada, LTD, 1975; and London: Bailliere Tindall, 1975). I assume an earlier edition was the pharmacology textbook that Dr. Fauci studied in his basic science years at Cornell University Medical College .

The only remaining English language traditional comprehensive textbook of internal medicine today that I know of is the: 21st Edition, HARRISON'S PRINCIPLES OF INTERNAL MEDICINE, 21st edition, Loscalzo J, Kasper DL, Longo DL, Fauci AS, Hauser SL, Jameson JL, eds. (New York: McGraw Hill, 2022), two volumes, 3855 pages of text. Dr. Fauci has been an editor eleven times of Harrison's since 1986 and was the Editor-in-Chief, Editions 14, 17. When I was a medical student at Saint Louis University School of Medicine (roughly a decade after Dr. Fauci's medical school experience) one of the three comprehensive major textbooks in internal medicine available at the time at was *Harrison's Principles of Internal Medicine*, 8th Edition, Thorn GW, Adams RD, Braunwald E, Isselbacher KJ, Petersdorf RG, eds. (New York: McGraw-Hill Book Company, 1977) one volume, 2088 pages of text.) **None of the Harrison's....** from my version of 1977 used during medical school by me to the present 21st edition instruct a sequential algorithm in a straight-forward fashion how to treating a novel virus (never experienced before by Humans):

1. Identify, characterize, and elucidate the pathophysiology of the novel virus
2. Treat **ASAP e.g.: within 72 hours of diagnosis**: initially with exogenous **Passive Immunization** (Polyclonal Antibodies: Convalescent Plasma or Sera or today Monoclonal antibodies or antibody cocktails) in **synergy** with **antivirals** when they become available.
3. Supportive care (everything else) until resolution or death
4. **Active Immunization (vaccination)** is **PROPHYLACTIC ONLY** as the development of endogenous IgG immunoglobulin in the individual takes 14 - 21 days after vaccination.

Since *The White House* meeting of March 2, 2020 [ <https://www.c-span.org/video/?469926-1/president-trump-meeting-pharmaceutical-executives-coronavirus> ], U.S. Medicine has rejected for all the treatment of *Passive Immunization early (within 72 - 120 hours) in the treatment of all COVID-19 infected patients and have administered at the wrong time and rationed to only the severely ill and those with specific concomitant disorders based on a misinterpretation of an epidemiologic article from Wuhan, China in JAMA of February 24, 2020.* [ [https://notifylibrary.org/sites/default/files/Investigational%20COVID-19%20Convalescent%20Plasma%20-%20Emergency%20INDs%20\\_%20FDA.pdf](https://notifylibrary.org/sites/default/files/Investigational%20COVID-19%20Convalescent%20Plasma%20-%20Emergency%20INDs%20_%20FDA.pdf) ]

Book 1, 1-1266 pages: *Dear Mr. President: COVID-19 and Where We Went Wrong* is:

- (1) an outline of the pathophysiology of COVID-19 including mortality rate per age from aggregate CDC data;
- (2) chronologic evaluation of COVID-19 convalescent plasma and subsequent inappropriate, underpowered, skewed, invalid FDA report in NEJM **erroneously** discrediting COVID-19 Convalescent Plasma on Nov 18, 2021: Gupta A, Gonzalez-Rojas Y, Juarez E, Casal MC, Moya J, Falci DR, Sarkis E, Solis J, Zheng H, Scott N, Cathcart AL, Hebner CM, Sager J, Mogailian E, Tipple C, Peppercon Alexander E, Pag PS, Free A, Brinson C, Aldinger M, Shapiro AE, for the COMET-ICE Investigators: Early treatment for Covid-19 SARS-Cov-2 neutralizing antibody Sotrovimab. N Engl J Med 2021 Nov 18; 385 (21): 1941-1950. <https://www.nejm.org/doi/pdf/10.1056/NEJMoa2107934?articleTools=true> ;
- (3) FDA, NIH, and VA **erroneous** disregard for the only FDA Approved antiviral, VEKLURY (Remdesivir), NDA #214878, since October 22, 2020;
- (4) illegal promotion of EUA antivirals (Paxlovid, etc) by commercial advertizing in deference to remdesivir--the only FDA-approved antiviral;
- (5) the NIH wholesale **absolute avoidance and illegal violation of patient rights by never implementing** of the Right to Try Act, PL 115-176; and
- (6) the continuous **unethical** persistent mandate for **placebo-only RCTs by the FDA and the NIH** in violation of the Nuremburg Code, the Helsinki Accords, and the Belmont Report.

**Mr. Secretary and Mr. President**, greater than 1,000,000 COVID-19 infected individuals in the United States of America from March 2020 to the present reportedly have died at the hands of **Chronic Denial nihilistic medicine** by the FDA, NIH, VHA, and Academic Medicine championing the withholding of immunologics and antivirals and promoting administrations late-in-the-disease during the cytokine cascade and the bradykinin storm instead during the viremic phase within 72 -120 hours from the contraction of the disease. -- Charles H. Andrus, M.D., F.A.C.S.

The above letter was referred to the author of the Sounding Board article in question, who offers the following reply:

*To the Editor:* I hesitate to reply to the comments of Drs. Bornstein and Volpintesta on my medical-humanities course, for I agree with so much of what they say. I agree that it would be ideal if all prospective medical students had the advantage of a wide background in humanities. I also concur that the student-selection process "should search for more broadly educated students whose education or personal inclination has already acquainted them with the humanities." And I am sympathetic with the view that humanism is a "life force" that sustains the student and the doctor, although I see science as a partner and not an enemy in this pursuit.

It would be a rather limited (and "misdirected") achievement if a humanities course were designed simply to improve the doctor-patient relation. Mine certainly isn't. We consider the widest range of human issues (personal, communal and professional), and we even try to uncover some of the mysteries locked in literature.

What puzzles me about the correspondents' reservations is this: why do the advantages of studying humanities cease after teen-age? Pope's couplet

'Tis the education forms the common mind:  
Just as the twig is bent, the tree's inclined

captured the 18th-century attitude to education. Today, we try to be a little less wooden.

I find it neither "unnatural" nor "inappropriate" that medical students should consider the humanities at a time in their course when they are confronted with deep human problems and emotions, and at an age when they have achieved a greater integration of their personalities. One of the students said, "I must admit that in all my schooling I had never gained such a deep insight into poetry and English literary extracts as I gained in these sessions. I guess it's a sign of maturity, for such material, if presented to me while at high school, would have been ridiculed."

Perhaps the ideal we all wish for is unattainable, but my course was motivated by Shelley's sentiment that "a thing is good in that it tends to produce that which though impossible, yet were it possible, would be desirable."

Melbourne,  
Victoria 3050, Australia

ANTHONY R. MOORE,  
M.B., F.R.A.C.S., B.A. (Camb.)  
University of Melbourne

#### A CASE OF CHRONIC DENIAL

*To the Editor:* The syndrome of "chronic denial" should be called to the attention of all university-affiliated physicians and personnel. The course of the affliction runs rampant through medical-school classes, as most students undoubtedly know, but to my knowledge has never been adequately described.

Primary symptoms of the chronic-denial student include such trite expressions as "I hardly got anything done in my seven hours of studying last night!" and "I only got to read a few pages of Goodman and Gilman for the test!" and "There's so much to read, I don't know how I'll ever get it done." The afflicted student might surface from the endless mental treks through the human morass on Saturday evening, but only because of peer-group pressure to prove to his or her fellow compatriots that "I don't study all the time!"

Pathognomonic of the "chronic-denial syndrome" is the student who can always be found in the classroom or library studying away the hours and at the same moment informing you of how little he ever accomplishes and how he wishes he were like so-and-so and what he might be doing this weekend.

Complications to this syndrome are primarily manifested in other students. It drives us crazy!

St. Louis, MO 63110

EDWARD J. LYNCH  
St. Louis University  
School of Medicine

## BOOK REVIEWS

**Paediatric Neurology for the Clinician** (Spastics International Medical Publications, Clinics in Developmental Medicine, No. 59/60). By Neil Gordon. 280 pp., illustrated. Philadelphia: J.B. Lippincott, 1976. \$28.75.

"It has been estimated that a third of all paediatric consultations involve damage to the nervous system." Spastics International Medical Publications must assume a major share of the responsibility for letting this book reach the market. An attractive title and high-quality paper evoke favorable comments.

From the title page, which omits the author's affiliations and qualifications, inadequacies abound. Fourteen chapters encompass only 263 pages of substantive text. The author's disclaimers of emphasis on patients commonly seen by the practitioner are contradicted by the chapters on neurologic disorders complicating general medical condition, emotional and functional disorders, disorders and diseases of the motor system and degenerative cerebral diseases. The style, awkward and ungrammatical, obscures meaning. References, most from 1970 and earlier, generally reflect neither original description nor comprehensive review. Eight pages are devoted to a useless name index, and only five pages are allowed for the subject index, which is grossly inadequate. For example, Zangwill, whatever his other attributes, appears in the name index only because he is the third author in a cited paper.

The effort needed to decipher the text exposes errors and omissions averaging at least one per page — e.g., diastematomyelia "is a developmental anomaly for which nothing can be done." No mention whatsoever is made of the prominent mirroring in Klippel-Feil syndrome. Gordon believes that Werdnig-Hoffman paralysis may have an acute onset in infancy. Sentences such as "Loss of already acquired speech is always a worry" and "The epileptic activity involves the diencephalon, a part of the brain sometimes referred to as 'the seat of consciousness'" indicate not only undisciplined language and thought but also neurologic naïveté.

Illustrations are often poorly chosen. The youngster with Turner's syndrome on page 29 exhibits prominent secondary sex characteristics, including breasts and pubic hair. The child with de Lange's syndrome does not have a prominent synophrys, and the child alleged to have Hurler's syndrome appears normal. The child with anencephaly has, instead, an apparent encephalocele. Where is the equinus in the talipes equinovarus? The patient with alleged idiopathic infantile hypercalcaemia almost did not make it into the picture. There are more than a few misspellings (ocular, heper-an).

Spastics International Medical Publications should consider a recent American phenomenon: general factory recalls have been issued for products with fewer defects and flaws than this one.

Minneapolis, MN 55455

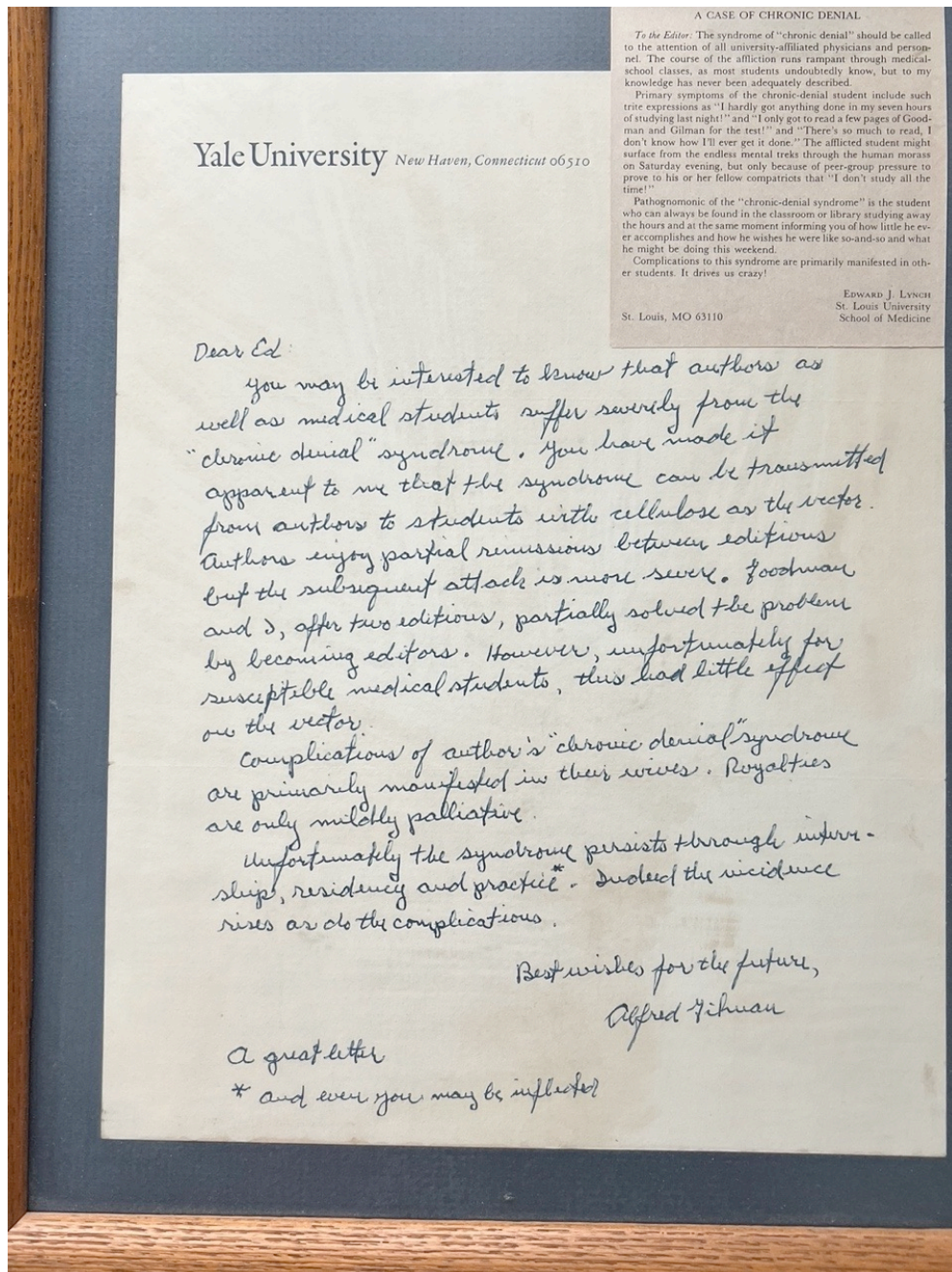
LAWRENCE A. LOCKMAN, M.D.  
University of Minnesota  
Medical School

**On the Shoulders of Giants: Notable names in hand surgery.** By Joseph H. Boyes, M.D. 222 pp., illustrated. Philadelphia: J.B. Lippincott, 1976. \$20.00.

The author, one of the founders of the specialty of surgery of the hand, presents a study of the sources of the known eponyms used in the anatomy and surgery of the hand, and acquaints the reader with the great surgeons and anatomists of the past responsible for the eponyms and the circumstances leading to their appearance. The book is a brilliant and concise history of the development of surgery of the hand, with description of the achievements, contributions and history of the surgeons and anatomists, and the circumstances behind them.

The historical data extend to description of individual characteristics and personal traits of these "giants." The book starts with the 16th century and continues to the present. Only those whose contributions are complete are included. The clear, lucid, literary style and the art of expression make the reading most rewarding. The book includes many illustrations — portraits of the great contrib-





Yale University New Haven, Connecticut 06510

Dear Ed

You may be interested to know that authors as well as medical students suffer severely from the "chronic denial" syndrome. You have made it apparent to me that the syndrome can be transmitted from authors to students with cellulose as the vector. authors enjoy partial remissions between additions but the subsequent attack is more severe. Goodman and I, offer two editions, Actually solved the problem by becoming editors. however, unfortunately for susceptible medical students, this had little effect on the vector.

Complications of authors "chronic denial" syndrome are primarily manifested in their wives. Royalties are only mildly palliative.

Unfortunately the syndrome persists through internship, residency and practice.\* ndeed the incidence rises has do the complications.

A great letter

\*and ever you may be infected

Best wishes for the future,

Alfred Gilman

Dear Mr. President:

You and I are anachronisms in our own time. On September 1<sup>st</sup> 2022, you gave an outstanding speech on democracy in front of the backdrop of Independence (Constitutional) Hall. <https://www.youtube.com/watch?v=F75ZMPRA9QY> Your advisors and yourself made the assumption that championing democracy before the physical-foundational epitomization of the origins of Our Democracy would make an impression on the vast majority of the people of the United States. You were wrong! In fact, the major commercial networks ABC, CBS, and NBC chose not to run your speech and instead ran commercial fiction of *Press Your Luck* and reruns of *Young Sheldon*, and *Law and Order*, respectively. <https://deadline.com/2022/09/joe-biden-speech-primetime-broadcast-networks-1235105916/> You were outstanding in noting the person who throughout your speech yelled out: F\_\_k Joe Biden, was and is protected by the 1<sup>st</sup> Amendment to the Constitution. <https://nypost.com/2022/09/01/heckler-chants-f-k-joe-biden-throughout-primetime-speech/> The three major news networks omitting your speech in primetime may be *de facto* in violation of their moral mandate to speak, report, and spread truth and decency, but such acts of omission and negating their mandate are protected also by the 1<sup>st</sup> Amendment. My personal right as an American under the 1<sup>st</sup> Amendment to the Constitution is to proclaim their omission of not carrying your speech as reprehensible and admonishing them to apologize to you and the American people for abrogating their responsibility as a Free Press guaranteed by the 1<sup>st</sup> Amendment.

Today, Mr. President, those that cry loudest--right or wrong--hold the stage and are steadfastly intolerant of others questioning their application of their First Amendment rights. Mr. President, you were Constitutionally right in challenging the hackler of your message while still affirming his right to say it:

*Americans have often made the greatest progress coming out of some of our darkest moments, like you are hearing in that bullhorn. And then later stating: Good manners is nothing they've ever suffered from.*

If today one questions the hecklers of our democracy, one risks their personal indignation and subsequent potential threatening response which is consistent with their interpretation of the 1<sup>st</sup> Amendment. Abetted by intense digital rhetoric, accusations of a stolen election, and fascist-like threats throughout everyday America, the hecklers of our democracy today have unfortunately instilled fear into all of our hearts. FDR phrased it best in his first inaugural address: "...that the only thing we have to fear is fear itself – nameless, unreasoning, unjustified terror which paralyzes needed efforts to convert retreat into advance ...."

<https://www.archives.gov/education/lessons/fdr-inaugural> Throughout American today, intimidation and the fear of subjection to *ad hominem* attacks by fellow Americans are all too real. Your intended message last Thursday was unsuccessful of reaching the vast majority of Americans because you chose to confront President Trump on his own turf--a 7<sup>th</sup> grade narcissistic playground-bully who has seldom, if ever, been corrected in his life nor knows how to apologize. Speaker of the House, Congresswoman Nancy Pelosi, said it best that we need to pray for President Trump while not condoning the lies and incorrect insinuations, incorrect inuendo, and plain meanest he advocates. <https://www.youtube.com/watch?v=5yodlvO3Nnk>



Due to England and its colonies adopting the Gregorian calendar (abandoning the Julian calendar) in 1752, you and I in our grammar school days reveled in the hope of a holiday from school on February 22<sup>nd</sup> annually memorializing George Washington's birthday of February 11, 1731, on the Julian calendar

<https://www.archives.gov/legislative/features/washington#:~:text=George%20Washington%20was%20born%20in,days%20to%20February%2022%2C%201732> . President Washington's chopping down the cherry tree and not lying about it is a piece of possible Americana fiction immortalizing Washington's honesty. <https://www.nps.gov/articles/george-washington-and-the-cherry-tree.htm> . I sure, there is more truth in this possible American historical falsehood than in any of Mr. Trump's greater than 30,000 lies during the time of his Administration. <https://www.washingtonpost.com/politics/2021/01/24/trumps-false-or-misleading-claims-total-30573-over-four-years/> President Gerald Ford pardoned President Nixon over *Watergate* from all criminal prosecution so the country could move ahead which was extremely noble and necessary step for our country to heal and truly that of an America statesman; but it was political suicide costing him success in his future Presidential run. <https://www.jfklibrary.org/about-us/news-and-press/press-releases/profiles-in-courage-for-our-time> Civil litigation around *Watergate* persisted, though, until 1982. Like yourself and all the Presidents since 1982, while in office, President Trump had absolute immunity from civil prosecution because of the U.S. Supreme Court ruling in *Nixon v Fitzgerald* <https://supreme.justia.com/cases/federal/us/457/731/> . In 1982, in a 5 - 4 decision of the Burger Supreme Court, *Nixon v Fitzgerald* paved the way for what is occurring today much like the dye was cast by the Taney Supreme Court facilitating the United States' advancement to the Civil War in the *Dred Scott* decision <https://www.pbs.org/wgbh/aia/part4/4h2933.html> . (Apropos, recently historians have ranked President Trump (2017-2021) second to last before President James Buchanan (1857-1861) <https://www.washingtonpost.com/history/2021/06/30/presidential-rankings-2021-cspan-historians/>.) In the majority opinion in *Nixon v Fitzgerald*, two protections from potential abuses by future Presidents of the *Nixon v Fitzgerald* decision were advanced: the Constitutional Imperative of Impeachment and the oversight of the *Free Press*. Throughout his administration and to this day, President Trump has vociferated against all that is contrary to his perception of his life as "Fake News." Last Thursday by their abrogation of their public mandate to inform the American public in a non-bias way of current events, ABC News, CBS News, and NBC News failed the entire American public as they *de facto* corroborated and validated Mr. Trump's warped perception and ongoing presentation.

Unfortunately, Mr. President, not only did the network channels fail to air your speech, but I do not think you accomplished getting the intent of your Thursday night speech across to the vast majority Americans in which you restated twice: *We the People*.... While you and I as children were required to memorize the Preamble to the United States Constitution, the subsequent recent generations have not been compelled regarding such a memorization mandate:

*We the People* of the United States, in Order to form a more perfect Union, establish Justice, insure domestic Tranquility, provide for the common defense, promote the general Welfare, and secure the Blessings of Liberty to ourselves and our Posterity, do ordain and establish this Constitution of the United States of America. <https://www.archives.gov/founding-docs/constitution>

Over the last six years as a VHA physician and surgeon and a University Professor, on Attending rounds (especially on the weekends) I have asked such relevant questions regarding medical education and history as what is the significance of Johns Hopkins University, William Olser,

M.D., William Halsted, M.D., Louis Pasteur, Sir Alexander Fleming, Walter Reed, M.D. etc. with responses of universally blank faces of the residents and medical students of Saint Louis University School of Medicine and the Washington University School of Medicine. Over the last year, I have asked the question on rounds where does the expression: *We the People*... come from? There were usually the same blank stares and most who guessed voiced as the origin of *We the People*... to be: *The Declaration of Independence* (although one seemingly insightful student emphatically stated on rounds that as we were on VA property, *We the People*... must be a VA saying).

After the establishment of the VA Department of Medicine and Surgery, PL-79-293 in early January 1946, the subsequent establishment of the VA-University Affiliation by Policy Memorandum No. 2 of January 30, 1946, clearly defines and delimits responsibilities in the VA-University Affiliation:

**General Division of Responsibility: The Veterans' Administration retains full responsibility for the care of patients, including professional treatment, and the school of medicine accepts responsibility for all graduate education.**

Yet, the mindset of the Universities over the last 76 years in regards to the VA-University Affiliation (Policy Memorandum No. 2) was that of not limited just to education but Universities optimizing financial profitability and claimed clinical control. There has been a transition over the last 76 years from the U.S. Government paying the residents assigned to the VA directly--to the present in which the VA pays the Universities, so the residents are technically "WOC"--without compensation and thus not VA employees. Regardless of VA or non-VA Teaching Hospitals, in all states, the residents cannot be licensed for internship and thus are "practicing" as physicians-in-training under the "Teaching Hospital / University" temporary medical license. Subsequent to that first year of residency, each of the fifty state medical licensing boards determine how many years of accredited ACGME residency are required before a physician-in-training can apply for state licensure after completely all the testing steps of USMLE.

The United States Government through Medicare and the VA is the crucial major funding source for all Resident Medical Education in the United States today. Every Medicare Part A funded residency position is funded with an annual reimbursement of approximately \$110,000 to the "Teaching Hospital" and not the residency nor the individual resident directly—as the resident's salaries are in the range of \$50,000 to \$60,000 today, benefits count for another ~\$20,000, and malpractice coverage is variable (but most University Hospital programs are self-insured). Medicare Part A resident salary support is lucrative for the "Teaching Hospital." As was previously stated, when the residents are assigned to the VA, their salary-line is still funneled through the University, and thus they are not employees of the VA. (The VA makes up about 10% of the Federal Funding of resident salaries.)

United States Medical Education presently is unspoken manpower crisis with the graduation of too many MDs and DOs for too few residencies available:

1. The Balance Budget Act of 1997 capped the number of residencies that the U.S. Government finances through Medicare Part A.

2. Since the beginning of the new millennia, individual U.S. medical school enrollment has increased, new medical schools are being built, and there has been a net increase in M.D. graduates facing a governmental-financially capped residency system -- all subliminally encouraged by the U.S. Government.
3. Osteopathic medical schools have matriculated into mainstream U.S. medicine over the last two decades so their D.O. graduates are in direct competition with M.D. graduates for residency positions that are capped by the Balance Budget Act of 1997.
4. Success or failure in USMLE I testing of basic science knowledge of the individual medical student are no longer reported with numerically-graduated grading but are just "Pass" / "Fail." Vis-à-vis, residency Program Directors in choosing applicants to interview have the USMLE II score only for initial interview ranking. (Residency interviews have become more about: Who you know, rather than what you know.)
5. No medical student nor resident today is aware of the Libby Zion case, the Bell Commission, nor the reason for development of the ACGME "Core Competencies." The subsequent ACGME "Duty Hours" resulted blaming "tired" residents and never admitting that all "Teaching Hospitals" in the United States had defrauded the American people by Attending Physicians charging for patients care services under Medicare Part B when many times the Attending Physician were not present in-person supervising the resident. Billing for such services when the Attending Physician is physically absent is fraudulent "Double Billing" as the resident salaries are subsidized under Medicare Part A and the E&M or procedural/operative reimbursements are under Medicare Part B. Mr. President, the most tragic thing about this is from 1996 to 2006, the DHHS and DOJ audited "Teaching Hospitals", published documentation of fraudulent activities of some of the audits on the Internet under Physicians at Teaching Hospitals (PATH) audits, and fined the "Teaching Hospitals" at least ¼ billion dollars officially without ever bringing this fraudulent situation to the national consciousness. In short, Academic Medicine hunker downed, paid the fines, developed Compliance Offices at each teaching hospital site, and **NEVER APOLOGIZED TO THE AMERICAN PEOPLE.**

Today, there is **LITTLE VESTING** required of the resident-physician in caring for the individual patient. Physicians-in-training (residents) are discouraged or even admonished for staying late in the care of a patient due to ACGME Duty-Hour regulations. While Medicine is a Profession, residencies have *de facto* become shift work tradesmen apprenticeships with weekly hours capped at 80 hours per week, and guaranteed 4 days off a month regardless if the resident has only taken 1-2 weeks of vacation or sick leave that month. What is worse, while a large majority of residents don't have permanent state licenses and are definitely not on the medical staffs of the teaching hospitals of America, many Attending Teaching Physicians have subliminally abrogated their 24/7 patient care responsibilities/ accountability by permitting the physicians-in-training to "take charge": e.g., the Attending Physician-of-record may know little of the patient's daily hospital course; the residents may place a patient of another service on "the rounding list" and fail to inform the Attending Physician-of-record for days; and when a catastrophic event occurs, (arrest, major change-in-physiology, etc.) the resident fails to

notify the attending physician in a timely fashion because, in many instances, the attending physician, his/her department, or the residency program have permissively engendered a sense of not bothering the attending physicians at nights, weekends, or holidays.

6. Overall, Mr. President, the idealized imaginary / fictitious American doctor who: made house-calls; believed deeply and acted appropriately epitomizing the persona of the doctor-patient relationship; and the physician truly dedicated to each and every presenting patient have gone the way of the Dodo bird. Today, throughout the country, private internists have had their hospital admitting privileges removed so they no longer see their established patients of many years in the hospital; and the “hospitalist” and the “acute care / trauma surgeon” typify Academic Medicine which has become shift work. Mr. President, how would you like it if your family or you did not even know the names of the physicians who were caring for you? A hundred years ago, Francis W. Peabody, M.D. both encouraged and admonished physicians

<https://depts.washington.edu/medhmc/wordpress/wp-content/uploads/Peabody.html> :

...for the secret of the care of the patient is in caring for the patient...

7. Six years ago when I returned once again as a University Professor of Surgery and VHA Physician and Surgeon, superficially the issues of ghost surgery were resolved in Academic Medicine--both in non-VA Teaching Hospitals through initiates of the PATH audits and in the VA by revisions of VHA Handbook on Resident Supervision (1400.1 and 1400.01). My personal perception of discriminate stratified delivery (mainly financial grounds) of Medical Care to the haves versus the have-nots remains intact. What is most distressing is that medical school has become the final prize instead of a pathway for continued life-time learning for all physicians. In concert with time (duty hour) limitations imposed by the Liaison Committee for Medicine Education (LCME) and the Accreditation Council for Graduate Medical Education (ACGME), medical education is being directed toward a for-profit proprietary medical school status that was minimized, distained, and discarded by The Flexner Report of 1910 as outlined by Thomas P. Duffy, M.D. in *The Flexner Report – 100 Years Later*. Yale Journal of Biology and Medicine 84 (2011) pp. 269-276.  
[https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3178858/pdf/yjbm\\_84\\_3\\_269.pdf](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3178858/pdf/yjbm_84_3_269.pdf) The Report advocated a medical school based on “the Scientific Method” as Johns Hopkins University of the time. Rigorous analytical studies in the laboratory sciences like: Anatomy, Physiology, Pathology, Microbiology, and Pharmacology were mandated in the primary medical school years with then the progression to clinical years. A pervasive medical educational movement to integrate disease topics with the basic sciences into the first two years of medical school emphasizes specific diseases by decreasing personal analytic thinking. Foundational aspects of the laboratory sciences have become peripheral to the analytical thought process. When I have asked of the medical students in the last six years what basic science texts (or any medical text) they have purchased for their ongoing learning, uniformly the students have stated they have purchased no textbooks while in medical school while stating they can get it on the Internet.

8. Funding of University Research throughout the country is mainly dependent on the Federal Government. Throughout COVID-19, the ever-present risk of losing that funding has become the major impediment for to research transparency and honesty. As Drs. Collins and Fauci are still in the employ of the United States Government, I would suggest to you that you call them into your office and along with the present Commissioner of the FDA, Robert Califf, M.D., as well as, Peter Marks, M.D., PhD of the biologics division of the FDA and the former FDA Chief Scientist and now Deputy Surgeon General of the U.S.A., Rear Admiral Denise Hinton. Mr. President, ask them to explain a few fundamental definitions and answer some resultant questions that will arise in your mind. For example:

- a. Why did we require, emphasize, and insist on RCTs (Randomized Controlled Trials) during the COVID-19 epidemic over the last two years with placebos when we had thousands, if not millions of concurrent matched control patients infected with the coronavirus, SARS-CoV-2 for all clinical trials of biologics and pharmaceuticals in the treatment of the patients who contracted COVID-19. Is the mandate (bordering on coercion of placebos ethical in an epidemic with a disease of a high mortality rate when administered against the backdrop of the Nuremberg Code, the Helsinki Accords, and the Belmont Report?
- b. Dr. Fauci, why did you **not** object when Dr. Schleifer on March 2, 2020, [https://www.youtube.com/watch?v=31i6p\\_stzW8](https://www.youtube.com/watch?v=31i6p_stzW8) :

DR. SCHLEIFER: Well, so, we make passive vac- — vaccine and therapeutic — therapeutic. Our drug will be able to protect you. Whether or not you're infected, it'll protect you from getting infected. Or if you are infected, it would treat you. And the — we have just taken processes that normally take years — literally, years — and we put them end-to-end and now do them in weeks to months, which nobody else in the industry can do.

incorrectly defined **Passive Immunization** as Passive Vaccination (**an incorrect euphemism**) and by verbal slight-of-hand did not discuss polyclonal antibodies at the meeting? thus inhibiting discussion of possible mobilizing of the American Blood Banks (i.e.: coordinated by the American Red Cross) in plasma drives to collect, process, and distribute COVID-19 Convalescent Plasma to be administered **within 72 hours** of contraction/diagnosis in individuals infected with coronavirus, SARS-CoV-2?

- c. Why were blood bankers, the American Red Cross, and rank-and-file clinicians not invited to the meeting of March 2, 2020?
- d. Dr. Marks, why were you not forthcoming regarding the early (<72 hours) administration of COVID-19 Convalescent Plasma?
- e. Rear Admiral Hinton, while you issued the histories and advocacies for early administration of the antiviral Remdesivir and COVID-19 Convalescent Plasma



as you wrote about this in your continued issuance of EUAs, why did the FDA omit to share these histories with the PRESS?

- f. Ask Drs. Collins, Fauci, and Califf to help you understand the definitions and fuzzy thinking that occurred regarding:
  - i. Safety (Phase I) clinical trials and Efficacy (Phase II/III) clinical trials
  - ii. Implementation (non-existence) of the Right to Try Act of 2018, PL-115-176
  - iii. Expanded Access (Compassionate Use) and how data from Expanded Access cannot be used in the completion of a Phase I study
  - iv. Why the antiviral Paxlovid which you, Mr. President, received and you had difficulty pronouncing is not mentioned by name in any of the Pfizer television cartoon commercials promoting oral antivirals [hint: Paxlovid is still experimental under an EUA while Remdesivir (VEKLURY) is an approved FDA intravenous prescription drug (NDA#214787) since October 22, 2020. Under FTC and FDA guidelines, Pfizer advertising an experimental drug by name in deference to a prescription drug is probably illegal. In short, Gilead Pharmaceuticals could sue Pfizer for advertising Paxlovid in deference to Remdesivir. By the way Mr. President, your administration has purchased millions of 5-day units of dosages of Paxlovid for the Test and Treat program.]
  - v. Why has the FDA and the NIH electronically overwritten documents without outlining or distinguishing the corrections?
  - vi. Dr. Collins after the Anthrax incident 2001 was halted and the government was worried about the potential weaponization of small pox, did the U.S. PHS plan on vaccinating medical personal and first responders against small pox? (hint: Yes). Why didn't they proceed? (hint: several medical personnel in their 50s who had been vaccinated as children but had tested negative for small pox antibodies developed pericarditis and died.) Since the label on the vial in the treatment of monkey pox includes "small pox", is there a risk for pericarditis in those who were vaccinated as children for small pox. The present vials of vaccine are labelled Monkey Pox Small Pox <https://www.cdc.gov/poxvirus/monkeypox/files/interim-considerations/guidance-jynneos-prep-admin-alt-dosing.pdf>
  - vii. Since Regeneron Pharmaceutical's monoclonal cocktail was effective for about a year until the fall of 2021 when SARS-Cov-2 developed resistance, why hasn't Regeneron Pharmaceutical investigated and promoted a subsequent monoclonal cocktail as Dr. Schliefer pointed out

they had at least a 1000 isolated antibodies on March 2, 2020?  
[https://www.youtube.com/watch?v=31i6p\\_stzW8](https://www.youtube.com/watch?v=31i6p_stzW8)

- g. Could the FDA and the NIH organize a public conference to invite and educate the entire nation on how to correct aberrancies that occurred over the last two years in regards to the definitions that have been muddled and misapplied, the violation of individual American rights with the suspension of EMTALA and the disregard for the Right to Try Act of 2018, PL – 115-176; the disregard for immunotherapy before the general public in those who are infected with COVID; the disregard for the prescription antiviral for COVID-19: Remdesivir (VELKURY), NDA# ; and the administration of millions of doses of vaccines, antivirals, immunoglobulins, and biologics still as experimental drugs and biologics even though they could be declared by the FDA prescription therapeutics?

Mr. President, please excuse what seems to be wanderings without an organized purpose. I started this letter by stating that you and I are anachronisms in our time. American history—no matter the topic—has been for you and I an integral part of our daily education and foundational knowledge. While ignorance may be blissful transiently, all too often, we may traverse life down the wrong rabbit hole if we construct a house-of-cards. This present submission was initiated by the fact that VA retirement people cannot locate my existence at the Edward Hines, Jr. VAH as Chief of Surgery (1996-2002) of the tertiary VAMC in the Chicago area to appropriately calculate my pension which requires the averaging of my three highest consecutive annual salaries. Since I officially have been *misplaced or lost* (i.e.: my Official Personnel File (OPF) and cannot be located in the VA or the U.S. National Archives, **I have become an “unperson” from 1982 to 2002.**) There seems to be no accountable person in the U.S. Department of Veterans Affairs or the Veterans Health Administration who can direct the search for my existence as Chief of Surgery of the Edward Hines, Jr. VAH [which, in 1946, was the original site of the agreement between Paul Magnuson, M.D., F.A.C.S. and Charles Puestow, M.D., F.A.C.S. for introducing University (Northwestern University and the University of Illinois) faculty and surgery residents into the daily care of Veteran patients at Building 1 of the Edward Hines, Jr. VAH in Maywood, Illinois! Mr. President, did you know that the Hines VAH historically was not only the origin of the VA-University Affiliation but also had an airstrip on the property that Charles Lindbergh would every-other-day fly the air mail from St. Louis to Chicago? – that is why, the airplane that Charles Lindbergh flew solo across the Atlantic Ocean was: *The Spirit of St. Louis.*] While this cover letter has been arduous for you to read, my informing you of all contained in today’s submission is my duty, as a Physician and Surgeon of the Veterans Health Administration of the U.S. Department of Veterans Affairs, to the people of the United States of America and to you as their President. Like all federal employees of the Executive Branch of the Federal Government, I serve at the pleasure of the President of the United States of America. While I am not one of your personal advisors and just a VA Physician and Surgeon, I ask your permission to suggest the following:

1. Mr. President, please write an Executive Order to promote greater transparency in all non-classified Executive Branch documents, handbooks, policies, memos, etc. by ordering the following: (1) **STOP** all changes or destruction of Executive Branch URLs on official U.S. Government websites; (2) **STOP** all electronic overwriting of all non-classified Executive Branch documents, handbooks, policies, memos, etc. without documenting future electronic access to the previously rescinded documents, etc. of the Executive Branch of the U.S. Government; (3) Ask of each agency to reconstruct the electronic pathways to all non-classified previously overwritten documents or those websites where the URLs have been changed.
2. Suspend the concept of privatization of the Executive Branch of the Federal Government. (e.g.: the St. Louis VAMC employs a private firm to verify all third party billings—at least 70% of all E & M and procedural CPT code billings at present are rejected.
- 3.

In the mindset of the 1950's of "See one, Do one, Teach one" in the public hospital,







**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

National Institutes of Health  
National Institute of Allergy  
and Infectious Diseases  
Bethesda, Maryland 20892

June 10, 2020

Dr. Charles Andrus  
150 Emerald Green Court  
St. Louis, MO 63141

NIAID Case #12276

Dear Dr. Andrus:

Thank you for your recent fax directed to Anthony S. Fauci, M.D., director of the National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health. Due to his professional responsibilities, Dr. Fauci has asked me to respond on his behalf.

Thank you for sharing this information.

Sincerely,

Kara M. Harris, MPH  
Section Chief for Controlled Correspondence and Public Inquiries  
Legislative Affairs and Correspondence Management Branch  
Office of Communications and Government Relations  
National Institute of Allergy and Infectious Diseases  
National Institutes of Health

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150 Emerald Green Court  
St. Louis, MO. 63141  
314-455-9482

June 7, 2020

Anthony S. Fauci, M.D.  
Director of the U.S. NIAID  
U.S. National Institutes of Health  
U.S. Dept of Health & Human Services  
5601 Fishers Lane, MSC. 9806  
Bethesda, MD. 20892-9806

Phone: 310-496-5717  
FAX: 301-402-3573

Stephen Hahn, M.D.  
Commissioner, U.S. Food and  
Drug Administration  
U.S. Dept of Health & Human Services  
c/o CBER Ombudsman  
Center for Biologics Evaluation and  
Research (CBER)  
10903 New Hampshire Ave, W071-7240  
Silver Springs, MD. 20993-0002  
Phone: 301-796-8240

Re: Submission of: **Time: The Crucial Independent Variable of the COVID-19 Pandemic**

Dear Drs. Fauci and Hahn:

On April 5, 2020, I submitted to the President and yourselves, the attached correspondence advocating for establishment of a national program through the Blood Banks of America for:

...systematic collection and safety testing of convalescent plasma from COVID-19 survivors. Such a national coordinated project could provide possible subsequent initial passive immunization with convalescent plasma to those infected with the corona virus until each individual can develop his/her own serum antibodies over the immediate subsequent symptomatic 14-day period.

The U.S. Food and Drug Administration is now providing rapid response for eIND applications regarding convalescent plasma and also is participating in the collaboration with the Mayo Clinic for physician and site recruitment. I have attached a regression analysis comparing the aggregate results of the efforts of the last several months in containment and resolution of the COVID-19 epidemics in the countries of China, Italy, Spain, and the United States of America. At present, public and local physician knowledge of the FDA IND research protocols (including that of the Mayo Clinic convalescent plasma project) are not well-known. Thus, the motivation for the attached paper entitled:

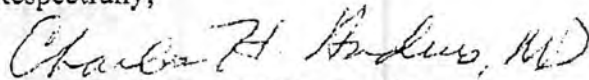
**Time: The Crucial Independent Variable of the COVID-19 Pandemic**

I will provide a CD containing the paper and Excel databases with the raw data and calculations so that the methodology can be critically evaluated. I will submit this cover letter and other cover letters with the manuscript (including tables and graphs) and attachments to the U.S. Copyright Office for recording for history this submission. As this is a submission to history and

not in regards for any personal gain, I waive all copyright protections regarding the reproduction of this paper. I hope this information will be helpful to you.

I will also submit this compilation to Catherine DeAngelis, M.D. and Jeffrey Drazen, M.D., former editors-in-chief of the *Journal of the American Medical Association* and *The New England Journal of Medicine* as their involvement—although they probably don't realize it--was helpful in my previous advocacy<sup>1-9</sup> to discontinue operations performed by surgery residents in the VA with the affiliated-University Attending Surgeon-of-Record *in absentia*. (Congress has never allowed for the Veterans Health Administration subvention—ability for the VA to bill Medicare— and thus Intermediary Letter-372 (Supervision Rules regarding Teaching Physicians of the U.S Department of Health and Human Services) does not directly apply to the Veterans Health Administration, U.S. Department of Veterans Affairs. Today, VHA Handbook 1400.01 no longer permits any elective or urgent operations to be performed by surgery residents without the Attending Surgeon-of-Record being physically present during at least the critical portions of every operation. Thank you for considering this submission.

Respectfully,

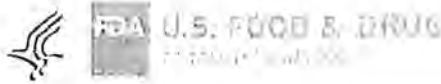


Charles H. Andrus, M.D., F.A.C.S.  
Professor, Department of Surgery, Saint Louis University School of Medicine  
Chief of the Unit II (SLU) General Surgery division,  
Surgical Service, John Cochran (St. Louis) VAMC

References 1-9: See attached titles from the U.S. Copyright office

Attachments:

1. Paper entitled: **Time: The Crucial Independent Variable** of the COVID-19 Pandemic
2. CD containing an electronic copy of the paper, the Excel databases
3. Copies of cover letters to other recipients
4. Copy of the submission of April 5, 2020



July 29, 2020

Dr. Charles H. Andrus  
150 Emerald Green Court  
St. Louis, MO 63141

Dear Dr. Andrus:

Thank you for your letter seeking information from the Food and Drug Administration (FDA) and the National Institutes of Health regarding the clinical development, safe use and availability of convalescent plasma collected from individuals who have recovered from Coronavirus Disease 2019 (COVID-19).

We appreciate your interest in this important topic and hope that the following information will be helpful.

Because COVID-19 convalescent plasma has not yet been approved for use by FDA, it is regulated as an investigational product. Health care providers or acute care facilities should instead obtain COVID-19 convalescent plasma from an FDA-registered blood establishment and must participate in one of the pathways described below.

#### 1. Clinical Trials

Investigators wishing to study the use of convalescent plasma in a clinical trial should submit requests to FDA for investigational use under the traditional IND regulatory pathway (21 CFR Part 312). CBER's Office of Blood Research and Review is committed to engaging with sponsors and reviewing such requests expeditiously. During the COVID-19 pandemic, INDs may be submitted via email to [CBERDOCEMailSub@fda.hhs.gov](mailto:CBERDOCEMailSub@fda.hhs.gov)

#### 2. Expanded Access

An IND application for expanded access is an alternative for use of COVID-19 convalescent plasma for patients with serious or immediately life-threatening COVID-19 disease who are not eligible or who are unable to participate in randomized clinical trials (21 CFR 312.305). FDA has worked with multiple federal partners and academia to open an expanded access protocol to facilitate access to COVID-19 convalescent plasma across the nation. Access to this investigational product may be available through participation of acute care facilities in an investigational expanded access protocol under an IND that is already in place.

Currently, the following protocol is in place: [National Expanded Access Treatment Protocol](#)

Further information, including a protocol summary, are available at:

<https://www.uscovidplasma.org/>

<https://www.uscovidplasma.org/pdf/COVID-19%20Plasma%20EAP.pdf>

#### 3. Single Patient Emergency IND

Although participation in clinical trials or an expanded access program are ways for patients to obtain access to convalescent plasma, for various reasons these may not be readily available to all patients in potential need. Therefore, given the public health emergency that the COVID-19 pandemic presents, and while clinical trials are being conducted and a national expanded access protocol is available, FDA also is facilitating access to COVID-19 convalescent plasma for use in patients with serious or immediately life-threatening COVID-19 infections through the process of the patient's physician requesting a single patient emergency IND (eIND) for the individual patient under 21 CFR 312.310. This process allows the use of an investigational drug for the treatment of an individual patient by a licensed physician upon FDA authorization, if the applicable regulatory criteria are met.

Note, in such case, a licensed physician seeking to administer COVID-19 convalescent plasma to an individual patient must request the eIND (see 21 CFR 312.310(b)).

Information about patient and donor eligibility can be found at:

<https://www.fda.gov/vaccines-blood-biologics/investigational-new-drug-and-device-application-idu-process-cber/recommendations-investigational-covid-19-convalescent-plasma>

Additional background about COVID-19 is available on the FDA website at:

<https://www.fda.gov/emergencypreparedness-and-response/coronavirus-and-emerging-threats/coronavirus-disease-2019-covid-19>

We hope this information is helpful. If you have questions, please feel free to contact us at [ocou@fda.hhs.gov](mailto:ocou@fda.hhs.gov) or by phone at 1-800-835-4709.

Sincerely,

Laura B. Carter, MD  
Carter, MD

Laura Carter  
Health Communications Specialist  
Center for Biologics Evaluation and Research  
Office of Communications, Outreach and Development  
U.S. Food and Drug Administration  
Tel: 800-835-4709  
[OCOD@fda.hhs.gov](mailto:OCOD@fda.hhs.gov)



*This informal communication represents my best judgment at this time. It does not constitute an advisory opinion in accordance with 21 CFR 10.85, and does not necessarily represent the formal position of FDA or otherwise obligate the agency to the views expressed.*

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SILVER SPRING MD 20903

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	<b>MO 630 9-41</b> 	<b>UPS NEXT DAY AIR SAVER 1P</b> TRACKING #: 1Z 8WF 343 13 9413 4202
		
BILLING: P/P		
CENTER: CBER Center/Office: cber/om	 CS 12.0 11 INTNVS 031 14 07/2020	





September 14, 2020

Charles Andrus, M.D., F.A.C.S.  
Saint Louis University  
Health Sciences Center, School of Medicine  
Department of Surgery  
150 Emerald Green Ct.  
St. Louis, MO 63141

Dear Dr. Andrus,

Thank you for your inquiry regarding COVID-19 convalescent plasma. The FDA appreciates your concerns about ensuring access to COVID-19 convalescent plasma during the public health emergency. Your inquiry was forwarded to the FDA's Center for Biologics Evaluation and Research for response.

As noted in your letter, since April 2020, the FDA has facilitated access to investigational COVID-19 convalescent plasma through several investigational pathways. A national expanded access program was initiated in early April to fill an urgent need to provide patient access to a medical product of possible benefit during a time that the FDA was working with researchers to facilitate the initiation of randomized clinical trials to study convalescent plasma. The program was developed with funding from the HHS' Biomedical Advanced Research and Development Authority (BARDA), with the Mayo Clinic serving as the lead institution. The program has facilitated the transfusion of over 70,000 patients with convalescent plasma. The FDA has also facilitated access to convalescent plasma for treating COVID-19 through traditional clinical trials and emergency single-patient investigational new drug (IND) applications.

On August 23, 2020, in response to the public health emergency and the FDA's extensive review of the science and data generated over the past several months, the agency issued an emergency use authorization (EUA) for investigational COVID-19 convalescent plasma for the treatment of hospitalized patients with COVID-19. The Letter of Authorization and associated materials are available at: <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs>.

In deciding to move forward with the EUA, the FDA determined that it was reasonable to believe that COVID-19 convalescent plasma may be effective in lessening the severity or shortening the length of COVID-19 illness in some hospitalized patients. The agency also determined that the known and potential benefits of the product, when used to treat COVID-19, outweigh the known and potential risks of the product and that there are no adequate, approved, and available alternative treatments.



The EUA is not intended to replace randomized clinical trials and facilitating the enrollment of patients into any of the ongoing clinical trials is critically important for the definitive demonstration of safety and efficacy of COVID-19 convalescent plasma. The FDA continues to recommend that the designs of ongoing randomized clinical trials of COVID-19 convalescent plasma and other therapeutic agents remain unaltered, as COVID-19 convalescent plasma does not yet represent a new standard of care based on the current available evidence.

Given the paucity of alternative treatments, the EUA is intended to improve the availability of COVID-19 convalescent plasma, while the FDA continues to work with researchers to conduct the clinical trials necessary for the definitive demonstration of COVID-19 convalescent plasma efficacy.

Additionally, on September 2, 2020, the FDA revised guidance entitled, "Investigational COVID-19 Convalescent Plasma" to provide recommendations to health care providers and investigators on the use of COVID-19 convalescent plasma under the EUA or investigational convalescent plasma under an IND during the public health emergency. The guidance supersedes the guidance of the same name dated April 2020, and updated in May 2020, and provides additional information related to the recently issued EUA for the use of COVID-19 convalescent plasma to treat hospitalized patients with COVID-19, including a discussion to facilitate the availability of this product when blood establishments, hospitals, and health care providers collect plasma that does not meet the Conditions of Authorization of the EUA.

The guidance also describes FDA's interim compliance and enforcement policy regarding the IND requirements for the use of investigational convalescent plasma. The guidance explains that during this period of enforcement discretion and beyond, the FDA will continue to work with any investigators who wish to submit INDs for the study of investigational convalescent plasma. Health care providers are encouraged to enroll patients and complete clinical trials.

In closing, we want to take this opportunity to thank you and your colleagues for treating COVID-19 patients and your interest in advocating on your patients' behalf.

Sincerely,

Jill S. Burkoff -S

Digitally signed by Jill S. Burkoff -S  
DN: cn=Jill S. Burkoff -S, ou=U.S. Government, ou=HHS, ou=FDA,  
ou=FDA, o=U.S. Government, ou=HHS, ou=FDA,  
cn=Jill S. Burkoff -S  
Date: 2020.09.14 10:13:02 -0400

Jill Burkoff

Health Communications Specialist

Center for Biologics Evaluation and Research  
Office of Communication, Outreach and Development  
U.S. Food and Drug Administration  
Tel: 240-402-8021  
[OCOD@fda.hhs.gov](mailto:OCOD@fda.hhs.gov)

U.S. Food & Drug Administration  
10903 New Hampshire Avenue Silver Spring,  
MD 20993 [www.fda.gov](http://www.fda.gov)

National Institute of Allergy and Infectious Diseases  
NATIONAL INSTITUTES OF HEALTH

Office of Communications and Government Relations  
5601 Fishers Lane, MSC 9806  
Bethesda, MD 20892-9806

DEPARTMENT OF HEALTH AND HUMAN SERVICES

RETURN ADDRESS CORRECTION REQUESTED

Official Business

Penalty for Private Use, \$300

Dr. Charles Andrus  
150 Emerald Green Court  
St. Louis, MO 63141



6/5/2021

0.99 Attachment VIII NIH and FDA responses including 6-10-2020 re NIAID Case #12276  
RE: Thank you Dr. Birx for your discussion on Face the Nation of 1/24/2021

10 of 10

**From:** afauci@niaid.nih.gov,

**To:** candrus600@aol.com,

**Subject:** RE: Thank you Dr. Birx for your discussion on Face the Nation of 1/24/2021

**Date:** Mon, Feb 15, 2021 10:57 am

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My work with the Coronavirus Task Force and the large volume of incoming emails precludes me or my staff from answering each individual message. I would encourage you to visit [www.coronavirus.gov](http://www.coronavirus.gov) for the latest information and guidance related to COVID-19.

Thank you, and best regards.

Anthony S. Fauci, M.D.

## **A COVID-19 Treatment Timeline Bibliography: *Passive Immunization and Antiviral Agents***

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- 3) 1776-07-04 Jefferson T: *Declaration of Independence*. U.S. National Archives. [https://www.archives.gov/founding-docs/downloads?\\_ga=2.962417.190847131.1641315284-75845464.1641315284](https://www.archives.gov/founding-docs/downloads?_ga=2.962417.190847131.1641315284-75845464.1641315284)
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**Prevention:** *Active Immunization:* Vaccines

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*such an important article that it has been copied and pasted to follow in its entirety. This is the NIH's justification of merging Phase I (safety) trials with Phase II (efficacy) trials so as to circumvent completely ever applying PL-115-176: The Right to Try Law with regards to COVID-19 Convalescent Plasma but also any future investigational drug or biologic ad infinitum. This obfuscation by the NIH is tantamount to justifying repeated violations of PL-115-176 and is ethically shameful!].*

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**Prevention:** *Active Immunization:* Vaccines

Sachdeva Y, Graber X, Kowal B, DiCioccio T, Stahl N, Lipsich L, Braunstein N, Herman G, Yancopoulos GD, for the Trial Investigators. REGN-COV2, a neutralizing antibody cocktail, in outpatients with Covid-19. December 17, 2021 NEJM.org, N Engl J Med 2021; 384:238-251. <https://www.nejm.org/doi/pdf/10.1056/NEJMe2034495?articleTools=true>

- 697) 2020-12-20 **Andrus CH**: E-mail submitted to Dr. Richard Stone, M.D., Chief Medical Executive (acting Under Secretary of the Veterans Health Administration), regarding the WRONG INCLUSION CRITERIA which contradicted the FDA directive of early administration in the course of COVID-19 disease (<72 hours from diagnosis) going forward from August 28, 2020 **to the present**, regarding Remdesivir (an FDA -approved licensed drug: NDA# 214787). This ERRONEOUS DIRECTIVE was still published on the Internet as of October 3, 2021—not having been retracted by the Veterans Health Administration (VHA)—**SHAME ON THE VHA!** The URL is no longer available. [https://vanf.app/CFU\\_PDF/Remdesivir\\_VEKLURY\\_November2020.pdf](https://vanf.app/CFU_PDF/Remdesivir_VEKLURY_November2020.pdf) What use to be at this U.S. Department of Veterans Affairs website is the following page that directed the administration of Remdesivir at the wrong time.
- 698) 2020-12-22 Pollard AJ, Bijker EM: A guide to vaccinology: from basic principles to new developments. Nature reviews immunology 2021; 21: 83-100. <https://www.nature.com/articles/s41577-020-00479-7>
- 699) 2020-12-23 Thomas K, Robbins R: What to know about the Covid antibody drugs that could help many. The New York Times, Updated Jan 12, 2021. <https://web.archive.org/web/20201223152514/https://www.nytimes.com/2020/12/23/health/covid-antibody-treatment.html>
- 700) 2020-12-24 **Andrus CH**: E-mail directed to the New England Journal of Medicine, the Veterans Health Administration, etc. It was ignored!
- 701) 2020-12-24 Goodman KE, Harris AD, Hoffmann DE: Legal challenges to allocating new COVID-19 antibody therapies to those who need them most. Health Affairs Blog. <https://www.healthaffairs.org/doi/10.1377/hblog20201222.609517/full/>
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- 704)** 2020-12-30 Britannica, The Editors of Encyclopaedia. “science”.: Seven Deadly Sins  
*Encyclopedia Britannica*, 31 Dec 2020, <https://www.britannica.com/science/science>.  
<https://www.britannica.com/topic/seven-deadly-sins>
- 705)** 2020-12-31 McGinley L: Only one covid-19 treatment is designed to keep people out of the hospital. Many overburdened hospitals are not offering it. Because of logistical challenges, only 20 percent of monoclonal antibodies distributed by the government have been used, officials say. The Washington Post  
<https://www.washingtonpost.com/health/2020/12/31/covid-monoclonal-antibodies-unused/>
- 706)** 2021-01-06 Libster R, Pérez Marc, Wappner D, Coviello S, Bianchi A, Braem V, Esteban I, Caballero MT, Wood C, Berrueta M, Rondan A, Lescano G, Cruz P, Ritou Y, Fernández Viña V, Alvarez Paggi D, Esperante S, Ferreti A, Ofman G, Ciganda A, Rodriguez R, Lantos J, Valentini R, Itcovici N, Hintze A, Oyarvide ML, Etcegarary C, Neira A, Name I, Alfonso J, López Castelo R, Caruso G, Rapelius S, Alvez F, Etchenique F, Dimase F, Alvarez D, Aranda SS, Sánchez Yanotti C, De Luca S, Baglivo J, Laudanno S, Nowogrodzki F, Larrea R, Silveyra M, Leberzstein G, Debonis A, Molinos J, González M, Perez E, Kreplak N, Pastor Argüello S, Gibbons L, Althabe F, Bergel E, Polack FP, for the Fundación INFANT-COVID-19 Group\*: Early high-titer plasma therapy to prevent severe Covid-19 in older adults, ClinicalTrials.gov, NCT04479163. New Engl J Med, NEJM.org, DOI: 10.1056/NEJMoa2033700, January 6, 2021, 1-9.  
<https://www.nejm.org/doi/pdf/10.1056/NEJMoa2033700?listPDF=true> Republished N Engl J Med, February 18, 2021; 384(7): 610 – 618.
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<https://www.fbi.gov/wanted/capitol-violence>
- 708)** 2021-01-08 BBC News-Science: What is blood plasma and how does it treat Covid-19?  
<https://www.bbc.com/news/av/science-environment-54665716>
- 709)** 2021-01-08 Eli Lilly and Company: 2020 Updates: Lilly’s global COVID-19 response.  
<https://www.lilly.com/news/stories/coronavirus-covid19-global-response>
- 710)** 2021-01-08 Hahn S: FDA commissioner Stephen Hahn MD speaks of the coronavirus response. <https://www.c-span.org/video/?507805-1/fda-commissioner-dr-stephen-hahn-coronavirus-response>
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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*  
**Prevention:** *Active Immunization:* Vaccines

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- 726) 2021-01-21 Eli Lilly announcement to stockholders: Lilly’s neutralizing antibody bamlanivimab (LY-CoV555) prevented COVID-19 at nursing homes in the BLAZE-2 trial, reducing risk by up to 80 percent for residents.  
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- 728) 2021-01-22 Acosta-Ampudia Y, Monsalve DM, Rojas M, Rodríguez Y, Gallo JE, Salazar-Uribe JC, Santander MJ, Cala MP, Zapata W, Zapata MI, Manrique R, Pardo-Oviedo JM, Camacho B, Ramírez-Santana C, Anaya JM, the CP-COVID-19 group. COVID-19

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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*  
**Prevention:** *Active Immunization:* Vaccines

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731) 2021-01-24 Kessler G, Rizzo S, Kelly M: Trump's false or misleading claims total 30,573 over 4 years. The Washington Post <https://web.archive.org/web/20210125221959/https://www.washingtonpost.com/politics/2021/01/24/trumps-false-or-misleading-claims-total-30573-over-four-years/>

732) 2021-01-26 Frontline: Trump's American Carnage. Season 2021, Episode 3. <https://www.pbs.org/video/trumps-american-carnage-cgbssm/>

733) 2021-01-26 Lilly Investors New Release: New data show treatment with Lilly's neutralizing antibodies bamlanivimab (LY-CoV555) and etesevimab (LY-CoV016) together reduced risk of COVID-19 hospitalizations and death by 70 percent. <https://investor.lilly.com/news-releases/news-release-details/new-data-show-treatment-lillys-neutralizing-antibodies>

734) 2021-01-29 Bodimer F: January 30<sup>th</sup> 2021 – Dr. Fred Buckhold, Dr. Bruce Hall, Dr. Rachel Presti & Katie Smith. <https://www.audible.com/pd/January-30th-2021-Dr-Fred-Buckhold-Dr-Bruce-Hall-Dr-Rachel-Presti-Katie-Smith-Podcast/B08TH5Z7PR>

735) 2021-01-31 Gray D: St. Louis hospital reports success using experimental COVID-19 Drug. KTVI <https://www.news10.com/news/st-louis-hospital-reports-success-using-experimental-covid-19-drug/>

736) 2021-02. Kaplan AP, Ghebrehiwet B: Pathways for bradykinin formation and interrelationship with complement as a cause of edematous lung in COVID-19 patients. J Allergy Clin Immunol 2021; 147: 507-509. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7598417/pdf/main.pdf>

737) 2021-02-01 Oxford Vaccine Group: Vaccine Knowledge Project. <https://vk.ovg.ox.ac.uk/vk/covid-19-vaccines>

738) 2021-02-01 Andrus CH:

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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*  
**Prevention:** *Active Immunization:* Vaccines

Dear Dr. Birx:

On March 24, 2020, while there was much discussion and debate about COVID-19 convalescent plasma and the possible development of monoclonal antibodies against COVID-19, U.S. Medicine and the Government failed to explain to the American public the differences and individual utilities of *Active Immunization* (vaccines to stimulate patient antibody production) and *Passive Immunization* (provision of convalescent plasmas, convalescence sera, and immunoglobins from other species providing already formed antibodies (IgM, IgG, and IgA) against the virus in COVID-19 immunologically naïve patients immediately within 72 hours of diagnosis (testing positive).

Etc—See attached letter to Dr. Birx.

- 739) 2021-02-02 U.S. Food & Drug Administration: CLINICAL MEMORANDUM, EUA 26382, COVID-19 Convalescent Plasma (CCP). **NONE OF THE VERSIONS OF THESE MEMOs are dated and thus dating was obtained from the digital captures using the Internet Archive (WayBack Machine).** The URL of this Memorandum is:  
<https://www.fda.gov/media/141480/download>

EXECUTIVE SUMMARY COVID-19 Convalescent Plasma (CCP), an unapproved biological product, is proposed for use under an Emergency Use Authorization (EUA) under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act), (21 USC 360bbb-3) as a passive immune therapy for the treatment of hospitalized patients with COVID-19, a serious or life-threatening disease. There currently is no adequate, approved, and available alternative to CCP for treating COVID-19. The sponsor has pointed to four lines of evidence to support that CCP may be effective in the treatment of hospitalized patients with COVID-19: 1) History of convalescent plasma for respiratory coronaviruses; 2) Evidence of preclinical safety and efficacy in animal models; 3) Published studies of the safety and efficacy of CCP; and 4) Data on safety and efficacy from the National Expanded Access Treatment Protocol (EAP) sponsored by the Mayo Clinic.

- 740) 2021-02-04 Hinton DM: U.S. Food and Drug Administration Letter to Nikki Bratcher-Bowman, Acting Assistant Secretary for Preparedness and Response, EUA-update regarding COVID-19 Convalescent plasma. February 4, 2021. (Please note that the position of Assistant Secretary of Preparedness and Response changed from February 2, 2021 (48 hours previous) from Robert Kadlec, M.D. who had been appointed by President Trump to an Acting Assistant Secretary for Preparedness and Response under the Biden Administration: Nikki Bratcher-Bowman.)  
<https://web.archive.org/web/20210218201225/https://www.fda.gov/media/141477/download>

- 741) 2021-02-04 U.S. Food & Drug Administration: FDA in Brief: FDA Updates Emergency Use Authorization for COVID-19 Convalescent Plasma to Reflect New Data, February 4, 2021. **This is deliberate legal obfuscation on the part of the FDA by stating that it was**

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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*  
**Prevention:** *Active Immunization:* Vaccines

limiting authorization-- *de facto*, the FDA was really expanding authorization by appropriately limiting the EUA for COVID-19 Convalescent Plasma to “early in the disease course” which was contrary to FDA directives from March 24, 2020 to September 2, 2020 when the criteria was that CCP could *only* be given to severe patients late in the disease course. The provision of CCP late in the disease course was *de facto* perpetuated by the fact that the FDA had unobtrusively removed the strict severity of illness criteria late in the disease course from all FDA documentation by overwriting on September 2, 2020 and going forward on all subsequent documentation and not announcing it *officially* to the U.S. Medical and Research Community, probably the rest of the Federal Government, and most definitely not to the American people. The “high dose” vs “low dose” concern is a secondary issue—that was used as a distraction by the FDA—as with monoclonal antibodies/antibody cocktails, COVID-19 Convalescent Plasma and monoclonal antibodies are all **Passive Immunization** and are therapeutically identical if given **EARLY IN THE COURSE OF THE DISEASE.**  
<https://www.fda.gov/news-events/fda-brief/fda-brief-fda-updates-emergency-use-authorization-covid-19-convalescent-plasma-reflect-new-data>

- 742) 2021-02-04. Cox D: The vaccine alternatives for people with compromised immune systems. National Geographic Science – Coronavirus. February 4, 2021.  
<https://www.nationalgeographic.com/science/article/the-vaccine-alternatives-for-people-with-compromised-immune-systems>
- 743) 2021-02-04 Roxby P: Covid: ‘Convalescent plasma no benefit to hospital patients.’ British Broadcasting Corporation (BBC) <https://www.bbc.com/news/health-55681051>
- 744) 2021-02-05 REGENERON: Regeneron reports fourth quarter and full year 2020 financial and operating results. <https://investor.regeneron.com/news-releases/news-release-details/regeneron-reports-fourth-quarter-and-full-year-2020-financial>
- 745) 2021-02-05 Yoon D: Enthusiasm fades for Covid-19 antibody treatments in South Korea – ‘We are hoping the treatment will lighten the burden of hospitalizing patients with serious symptoms’. The Wall Street Journal, Feb. 5, 2021 7:02 am ET.  
<https://www.wsj.com/articles/enthusiasm-fades-for-covid-19-antibody-treatments-in-south-korea-11612526555>
- 746) 2021-02-05 Dockser Marcus A: FDA Limits Use of Convalescent Plasma as Covid-19 Treatment. Agency to scale back authorization of the antibody-rich blood component after studies yielded mixed results. The Wall Street Journal Feb 5, 2021.  
<https://www.wsj.com/articles/fda-limits-use-of-convalescent-plasma-as-covid-19-treatment-11612537239>
- 747) 2021-02-06 Mershon M: Austin regional infusion center makes it easier for COVID-19 patients to get antibody therapy.

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<https://spectrumlocalnews.com/tx/austin/news/2021/02/05/austin-regional-infusion-center-makes-it-easier-for-covid-19-patients-to-get-antibody-therapy>

748) 2021-02-09 Kaka AS, MacDonald R, Greer N, Vela K, Duan-Porter W, Obley A, Wilt TJ: Major Update: Remdesivir for Adults with COVID-19 – A living systematic review and meta-analysis for the American College of Physicians practice points. Ann Internal Med <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7901604/pdf/aim-olf-M208148.pdf>

749) 2021-02-09 Hinton DM: Emergency Use Authorization 090 regarding Eli Lilly's bamlanivimab. U.S. Food & drug, February 9, 2021. <http://web.archive.org/web/20210210103943/https://www.fda.gov/media/143602/download>

750) 2021-02-09 Hinton DM: Emergency Use Authorization 094 regarding Eli Lilly's bamlanivimab and etesevimab. U.S. Food & drug, February 9, 2021. <https://web.archive.org/web/20210210011139/https://www.fda.gov/media/145801/download>

751) 2021-02-09 Food and Drug Administration: Coronavirus (COVID-19) update: FDA authorizes monoclonal antibody for treatment of COVID-19. FDA news release, February 09, 2021. <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-monoclonal-antibodies-treatment-covid-19-0>

752) 2021-02-09. Robbins R: Another antibody therapy is authorized for high-risk Covid-19 patients. The New York Times. Feb 9, 2021 <https://www.nytimes.com/2021/02/09/world/covid-coronavirus-lilly-antibody-treatment.html>

753) 2021-02-10 Walker M: FDA OKs antibody combo for milder COVID-19—Cut hospitalizations, deaths in patient at high risk of severe disease. MedPage Today. <https://www.medpagetoday.com/infectiousdisease/covid19/91136>

754) 2021-02-10 Deb P, Molla MA, Saif-Ur-Rahman KM: An update to monoclonal antibody as therapeutic option against COVID-19. Biosafety and Health 3 (2021) 87-91. <https://reader.elsevier.com/reader/sd/pii/S2590053621000197?token=FD34A188A49959EDC981030D0F27DC39F4B36AB43BF80B464007E21912B046DBD7AE761CDE51150083892C51D0C44880&originRegion=us-east-1&originCreation=20210726023159>

755) 2021-02-10 Anderson M: FDA restricts use of convalescent plasma to hospitalized COVID-19 patient. Becker's Hospital Review February 10, 2021. <https://www.beckershospitalreview.com/pharmacy/fda-restricts-use-of-convalescent-plasma-to-hospitalized-covid-19-patients.html>

756) 2021-02-10 Andrus C: Use of COVID-19 convalescent plasma EARLY in the course of the disease. ResearchGate [https://www.researchgate.net/post/Use\\_of\\_COVID-19\\_Convalescent\\_Plasma\\_EARLY\\_in\\_the\\_course\\_of\\_the\\_disease](https://www.researchgate.net/post/Use_of_COVID-19_Convalescent_Plasma_EARLY_in_the_course_of_the_disease)

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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*  
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way to the St. Louis (John Cochran division) VAMC to round on the Veteran patients of General Surgery II. Listening to this message epitomized that of which the concept of gratitude of Thanksgiving Day is engendered and our assurance by the Constitution and the Bill of Rights of our freedoms of which we all-to-often take for granted.)

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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*  
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<https://web.archive.org/web/20211222180424/https://www.fda.gov/media/155049/download>

PAXLOID is comprised of nirmatrelvir, a SARS-CoV-2 main protease (Mpro: also referred to as 3CLpro or nsp5 protease) inhibitor, co-packaged with ritonavir, an HIV-1 protease inhibitor and CYP3A inhibitor. Ritonavir, which has no activity against SARS-CoV-2 on its own, is included to inhibit the CYP3A-mediated metabolism of nirmatrelvir and consequently increase nirmatrelvir plasma concentrations to levels anticipated to inhibit SARS-CoV-2 replication. PAXLOID is not approved for any use, including for use for the treatment of COVID-19.

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#### Authorized Use

The FDA has authorized the emergency use of PAXLOVID, an investigational medicine, for the treatment of mild-to-moderate COVID-19 in adults and children (12 years of age and older weighing at least 88 pounds [40 kg]) with a positive test for the virus that causes COVID-19, and

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who are at high risk for progression to severe COVID-19, including hospitalization or death, under an EUA.

PAXLOVID is investigational because it is still being studied. There is limited information about the safety and effectiveness of using PAXLOVID to treat people with mild-to-moderate COVID-19. [https://www.covid19oralrx-patient.com/?source=google&HBX\\_PK=s\\_paxlovid&skwid=43700068270576697&gclid=EAIaIQobChMIIsIiA49fY9glV5JbCh0sx4PEAAAYASAAEgZs\\_D\\_BwE&gclid=aw.ds](https://www.covid19oralrx-patient.com/?source=google&HBX_PK=s_paxlovid&skwid=43700068270576697&gclid=EAIaIQobChMIIsIiA49fY9glV5JbCh0sx4PEAAAYASAAEgZs_D_BwE&gclid=aw.ds)

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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*  
**Prevention:** *Active Immunization:* Vaccines

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**1184)** 2022-05-12 Tin A: 1 million COVID deaths: Pandemic’s tragic toll in U.S. extends far beyond the numbers. CBS News <https://www.cbsnews.com/news/covid-deaths-1-million-us-pandemic-toll/>

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2022-05 Hart WS, Miller E, Andrews NJ, Waight P, Maini PK, Funk S, Thompson RN: Generation time of the alpha and delta SARS-CoV-2 variants: an epidemiological analysis. 2022 May; 10: 603 – 610. [https://www.thelancet.com/pdfs/journals/laninf/PIIS1473-3099\(22\)00001-9.pdf](https://www.thelancet.com/pdfs/journals/laninf/PIIS1473-3099(22)00001-9.pdf)

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Shuttleworth M: Hawthorne Effect. <https://explorable.com/hawthorne-effect#:~:text=The%20Hawthorne%20Effect%20and%20Industrial%20Psychology&text=If%20a%20group%20is%20isolated,%20C%20will%20skew%20the%20results.>

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## A COVID-19 Treatment Timeline Bibliography: *Passive Immunization and Antiviral Agents*

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- 2) 1599 Shakespeare: "...The play's the thing / Wherein I'll catch the conscience of the King." Hamlet, Act 2, Scene 2. <https://www.enotes.com/homework-help/what-does-hamlet-mean-when-he-says-the-play-s-the-685602>
- 3) 1776-07-04 Jefferson T: *Declaration of Independence*. U.S. National Archives. [https://www.archives.gov/founding-docs/downloads?\\_ga=2.962417.190847131.1641315284-75845464.1641315284](https://www.archives.gov/founding-docs/downloads?_ga=2.962417.190847131.1641315284-75845464.1641315284)
- 4) 1776-09-22 America's Library: Patriot Hale was hanged September 22, 1776. [http://www.americaslibrary.gov/jb/revolut/jb\\_revolut\\_hale\\_1.html](http://www.americaslibrary.gov/jb/revolut/jb_revolut_hale_1.html)
- 5) 1783 Madison J and the founders of the U.S.A.: The Constitution of the United States of America. <https://www.archives.gov/founding-docs/constitution>

We the People of the United States, in Order to form a more perfect Union, establish Justice, insure domestic Tranquility, provide for the common defense, promote the general Welfare, and secure the Blessings of Liberty to. Ourselves and our Posterity, do ordain and establish this Constitution for the United States of America. <https://www.archives.gov/founding-docs/constitution>

- 6) 1787-07-06 Jefferson T: Letter from Thomas Jefferson to Thomas Mann Randolph, Jr., Paris July 6, 1787. U.S. National Archives. <https://founders.archives.gov/documents/Jefferson/01-11-02-0475>

—but health, without which there is no happiness. An attention to health then should take place of every other object.

Constitutional Rights Foundation: Natural Rights: The Declaration of Independence and Natural Rights, Thomas Jefferson, drawing on the current thinking of his time, used natural rights ideas to justify declaring independence from England. (First written ~10/2008). <https://www.crf-usa.org/foundations-of-our-constitution/natural-rights.html#:~:text=Most%20scholars%20today%20believe%20that,of%20English%20philosopher%20John%20Locke.&text=Among%20these%20fundamental%20natural%20rights,%2C%20liberty%2C%20and%20property.%22>

- 7) 1837 Hans Christian Andersen: The Emperor's New Clothes. SDU, H.C. Andersen Centret. [https://andersen.sdu.dk/vaerk/hersholt/TheEmperorsNewClothes\\_e.html](https://andersen.sdu.dk/vaerk/hersholt/TheEmperorsNewClothes_e.html)

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**Prevention:** *Active Immunization:* Vaccines

- 8) 1865-03-04 Lincoln A: President Abraham Lincoln's Second Inaugural Address.  
OurDocuments <https://www.ourdocuments.gov/doc.php?flash=false&doc=38>

*With malice toward none; with charity for all; with firmness in the right, as God gives us to see the right, let us strive on to finish the work we are in; to bind up the nation's wounds; to care for him who shall have borne the battle, and for his widow, and his orphan—to do all which may achieve and cherish a just, and a lasting peace, among ourselves, and with all nations.*

- 9) 1865 Carroll, Lewis, (Charles Lutwidge Dogson) *Alice's Adventures in Wonderland*. London: MacMillan and Co., 1866. [https://www.etsy.com/listing/1018008039/dodgson-charles-lutwidge-lewis-carroll?gpla=1&gao=1&&utm\\_source=google&utm\\_medium=cpc&utm\\_campaign=shopping\\_us\\_a-books\\_movies\\_and\\_music-books-childrens\\_books&utm\\_custom1=\\_k\\_EAIaIQobChMIwKjN\\_s2T9QIVAHNvBB1qWwZMEAQYAyABEgJqavD\\_BwE\\_k\\_&utm\\_content=go\\_12573073822\\_126376635984\\_507798475344\\_aud-1185363470307:pla-352609785060\\_c\\_1018008039\\_468327882&utm\\_custom2=12573073822&gclid=EAIaIQobChMIwKjN\\_s2T9QIVAHNvBB1qWwZMEAQYAyABEgJqavD\\_BwE](https://www.etsy.com/listing/1018008039/dodgson-charles-lutwidge-lewis-carroll?gpla=1&gao=1&&utm_source=google&utm_medium=cpc&utm_campaign=shopping_us_a-books_movies_and_music-books-childrens_books&utm_custom1=_k_EAIaIQobChMIwKjN_s2T9QIVAHNvBB1qWwZMEAQYAyABEgJqavD_BwE_k_&utm_content=go_12573073822_126376635984_507798475344_aud-1185363470307:pla-352609785060_c_1018008039_468327882&utm_custom2=12573073822&gclid=EAIaIQobChMIwKjN_s2T9QIVAHNvBB1qWwZMEAQYAyABEgJqavD_BwE)
- 10) 1885 Twain M: First edition of the *Adventures of Huckleberry Finn* with an E.W. Kemble Illustration Laid In. New York: Charles L Webster and Company, 1885. (an early example of Twain's book.) <https://www.raptisrarebooks.com/product/adventures-of-huckleberry-finn-mark-twain-first-edition-1885/>
- 11) 1885-07-06 CDC: Historical perspectives a centennial celebration: Pasteur and the modern era of immunization. MMWR 9185 Jul 05; 34(26): 389-90. <https://www.cdc.gov/mmwr/preview/mmwrhtml/00000572.htm>
- 12) 1873 Saxe JG: *The Blind Men and the Elephant*. This was a retelling by the American poet John Godfrey Saxe of an Indian parable which epitomizes how individuals over the last several years with personal vested interests and self-promotion (e.g.: conflicts of interest to advance financial advancement, preserve the *status quo* with regards to research grants, misdirection of informed consents and continue coercion in research trials, etc.) have skewed the addressing of the COVID-19 pandemic for personal advancement. <https://www.commonlit.org/en/texts/the-blind-men-and-the-elephant>

It was six men of Indostan  
To learning much inclined,  
Who went to see the Elephant  
Though all of them blind,  
That each by observation  
Might satisfy his mind.

The First approached the Elephant  
And, happening to fall  
Against his broad and sturdy side,  
At once began to bawl:

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“God bless me, but the Elephant  
Is very like a wall!”

The Second, feeling the tusk  
Cried, “Ho! What have we here  
So very round and smooth and sharp?  
To me ‘tis very clear  
This wonder of an Elephant  
Is very like a spear!”

The Third approached the animal  
And, happening to take  
The squirming trunk within his hands,  
Thus boldly up he spake:  
“I see,” quoth he, “The Elephant  
Is very like a snake!”

The Fourth reached out an eager hand,  
And felt about the knee:  
“What most the wondrous beast is like  
Is very plain,” quoth he;  
“Tis clear enough the Elephant  
Is very like a tree!”

The Fifth, who chanced to touch the ear,  
Said, “Even the blindest man  
Can tell what this resembles most:  
Deny the fact who can:  
This marvel of an elephant  
Is very like a fan!”

The Sixth no sooner had begun  
About the beast to grope  
Then, seizing on the swinging tail  
That fell within his scope,  
“I see,” quoth he, “the Elephant  
Is very like a rope!”

And so these men of Indostan  
Disputed loud and long,  
Each in his own opinion  
Exceeding stiff and strong.

Though each was partly in right,  
They all were in the wrong!

- 13) 1887 Acton: Lord Acton writes to Bishop Creighton that the same moral standards should be applied to all men, political and religious leaders included, especially since “Power tends to corrupt and absolute power corrupts absolutely.” OLL <https://oll.libertyfund.org/quote/lord-acton-writes-to-bishop-creighton-that-the-same-moral-standards-should-be-applied-to-all->

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- 14) 1905 Santayana G: "Those who cannot remember the past are condemned to repeat it", *The Life of Reason*, 1905. From the series Great Ideas of Western Man. SAAM, Smithsonian American Art Museum. <https://americanart.si.edu/artwork/those-who-cannot-remember-past-are-condemned-repeat-it-george-santayana-life-reason-1905>
- 15) 1905 Robert E. Gross, M.D., born: Clatworthy HW: Robert E. Gross. <https://pubmed.ncbi.nlm.nih.gov/3095885/> and [https://fa.hms.harvard.edu/files/memorialminute\\_gross\\_robert\\_e.pdf](https://fa.hms.harvard.edu/files/memorialminute_gross_robert_e.pdf)
- 16) 1913 ACS: History of the American College of Surgeons. <https://www.facs.org/about-ac/archives/acshistory>
- 17) 1918-1919 CDC: History of the American College of Surgeons. <https://www.facs.org/about-ac/acs-history/>
- 18) 1926 de Kruif P: *Microbe Hunters*. New York: Harcourt, Brace, and Co., 1926. (New York: Paul de Kruif, Harcourt, Brace, Co., copyright renewed 1954). <https://laurieximenez.files.wordpress.com/2016/03/2-microbe-hunters-paul-de-kruif.pdf>
- 19) 1927-03-19 Peabody FW: The Care of the Patient. J Am Med Association. 1927 March 19; 88 (12): 877-882. (Presented at Boston Hospital, October 21, 1925). <https://depts.washington.edu/medhmc/wordpress/wp-content/uploads/Peabody.html>
- 20) 1933-03-04: Roosevelt FD: Inaugural Address of the President, Washington, D.C., March 4, 1933. <https://www.archives.gov/files/education/lessons/fdr-inaugural/images/address-1.gif>  
  

...So, first of all, let me assert my firm belief that the only thing we have to fear is fear itself – nameless, unreasoning, unjustified terror which paralyzes needed efforts to convert retreat to advances. In every dark hour of our national life a leadership of frankness and vigor has met with that understanding and support of the people themselves which is essential to victory. I am convinced that you will again give that support to leadership in these critical days.
- 21) 1937 Cronin AJ: *The Citadel*. Boston: Little, Brown & Co, 1937. Example: <https://www.antiqubook.com/search.php?action=search&author=CRONIN%20%20&title=The%20Citadel>
- 22) 1937 Farrow J: *Damien the Leper*. New York: Steel and Ward Inc., 1937. <https://www.biblio.com/damien-the-leper-by-farrow-john/work/77302>
- 23) 1939-10-19 Foster LR, Buchman S, Capra F: *Mr. Smith Goes to Washington*. Columbia Picture Corporation. <https://www.dailyscript.com/scripts/MrSmithGoesToWashington.txt>

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JEFFERSON

Just get up off the ground, that's all I ask. Get up there with that lady that is up on top of this Capitol dome--that lady that stands for liberty, take a look at this country through her eyes if you really want to see something and you won't just see scenery--you'll see the whole parade of what man's carved out for himself after centuries of fighting and fighting for something better than just jungle law, fighting he can stand on his own two feet-- free and decent, like he was created-- no matter what his race, color or creed. That's what you'll see. There's no place out there for graft or greed or lies or compromise with human liberties. And if that's what the grown-ups have done to this world that was given to them we'd better get those boy's camps started fast and see what the kids can do and it is not too late because this country is bigger than the Taylors, or you or me, or anything else. Great principles don't get lost once they come to light. They're right here. You just have to see them. ...

JEFFERSON (with effort)

I guess this is just another lost cause, Mr. Paine. All you people don't know about lost causes. Mr. Paine does. He said once they were the only causes worth fighting for, and he fought for them once, for the only reason that any man ever fights for them. Because of just one plain, simple rule, "Love thy neighbor," and in this world today, full of hatred, a man who knows that one rule has a great trust. You knew that rule, Mr. Paine, and I loved you for it, just as my father did. And you know that you fight for the lost causes harder than for any others. Yes, you'd even die for them, like a man we both know, Mr. Paine. You think I'm licked. You all think I'm licked. Well, I'm not licked and I'm going to stay right here and fight for this lost cause even if this room gets filled with lies like these, and the Taylors and all their armies come marching into this place. Somebody'll listen to me--some-- ...

- 24) 1940 DeAngelis CD (Former Editor-in-Chief, *Journal of the American Medical Association*): Biography. Changing the face of Medicine.

[https://cfmedicine.nlm.nih.gov/physicians/biography\\_77.html](https://cfmedicine.nlm.nih.gov/physicians/biography_77.html)

- 25) 1942 Cronin AJ: *The Keys of the Kingdom*. Pub: Alfred Scherz Berne, 1942.

[https://www.abebooks.com/servlet/SearchResults?an=cronin&cm\\_sp=sort-\\_SRP-\\_Results&fe=on&sortby=1&tn=keys%20kingdom](https://www.abebooks.com/servlet/SearchResults?an=cronin&cm_sp=sort-_SRP-_Results&fe=on&sortby=1&tn=keys%20kingdom)

- 26) 1944-06-25 Army Service Forces, Office of the Chief, Chemical Warfare Service, Gravelly Point, Washington, 25, D.C.

SPECIAL ORDERS)

25 June 1944

No. 152 )

1. The Chief of Chemical Warfare Service commends the officers and enlisted men who voluntarily submitted to tests conducted by the Medical Division. These men participated beyond the call of duty by subjecting themselves to pain, discomfort, and possible permanent injury for the advancement of research in protection for our armed forces. Those named below knowingly submitted to exposure to chemical agents for some period during the months designated:

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**Prevention:** *Active Immunization:* Vaccines

September and October, 1943

PVT. EARL L. ALEXANDER, JR, 35704460

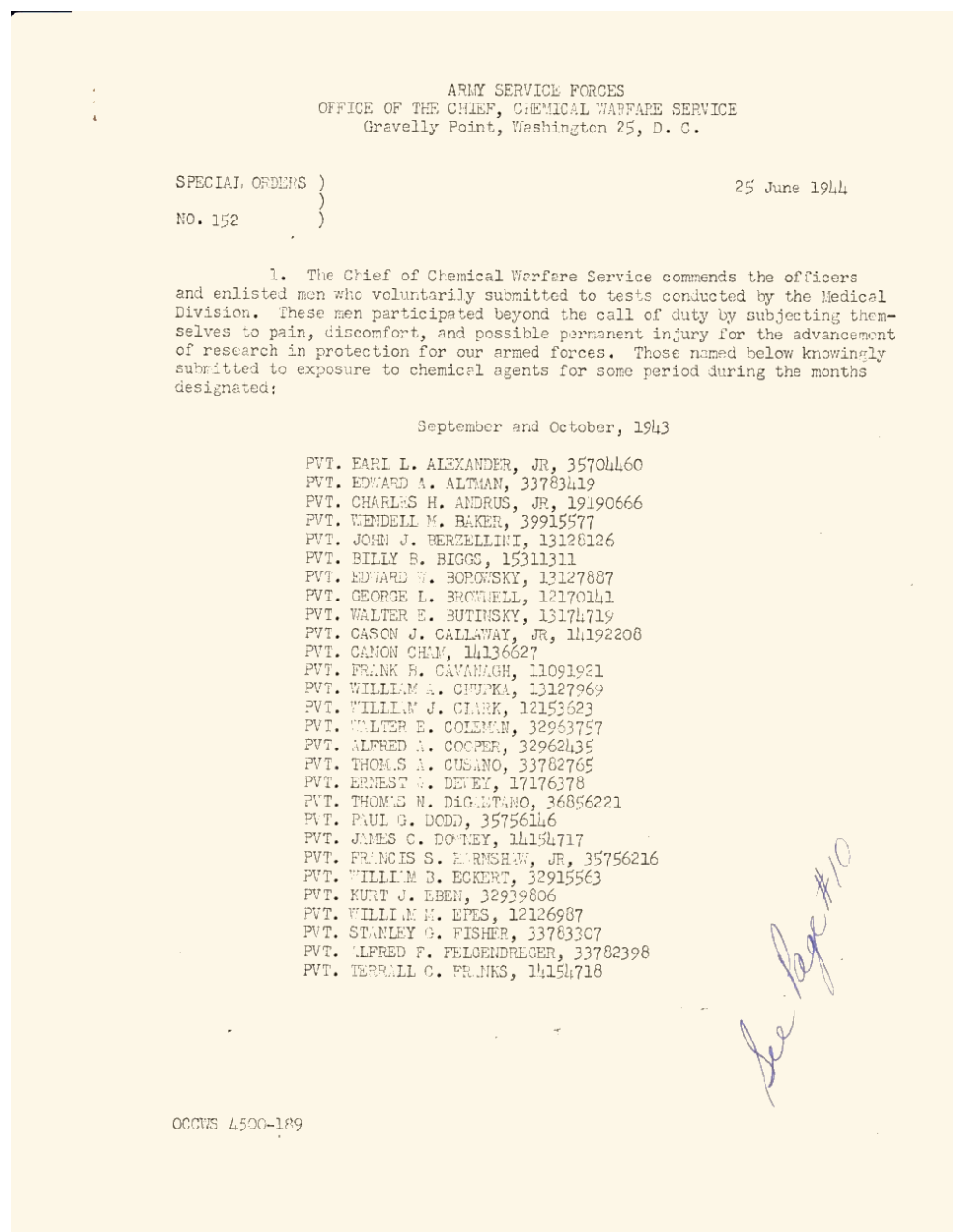
PVT. EDWARD A. ALTMAN, 33783419

PVT. CHARLES H. ANDRUS, JR, 1919066...

*PVT. CHARLES H. ANDRUS, JR, 1919066 was the father of Charles H. Andrus, III, M.D., F.A.C.S.* Obituary of Charles Hiram Andrus, Jr., April 30, 1921 – December 21, 2013  
<https://www.legacy.com/us/obituaries/sfgate/name/charles-andrus-obituary?id=17958880>

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From 2015-06-22 Dickerson C: Secret World War II Chemical Experiments Tested Troops By Race. (World War II Secret Mustard Gas Testing) NPR s|t|l|p|r June 22, 2015. <https://www.npr.org/2015/06/22/415194765/u-s-troops-tested-by-race-in-secret-world-war-ii-chemical-experiments> The original document above was the first page of a thirty-one page document that can be accessed by the hyperlink in the NPR document: Attached was a long list of names.

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- 27) 1944-10-25 Tillman B: The Gambier Bay's Final Hours. U.S. Naval Institute: Naval History Magazine 2019 Oct 33(5). <https://www.usni.org/magazines/naval-history-magazine/2019/october/gambier-bays-final-hours>
- 28) 1946 Orwell G: *Animal Farm* New York: Harcourt, Brace and Company, 1946. <https://www.worldcat.org/title/animal-farm/oclc/366597>
- 29) 1946-01-03 PL-79-293 authorizes the Department of Medicine and Surgery at the Veterans Administration. [2015-01-31 We Served Too: VA history: VA's Department of Medicine and Surgery established. <https://weservedtoo.wordpress.com/2015/01/31/va-history-vas-department-of-medicine-and-surgery-established/>
- 30) 1946-01-31 U.S. Department of Veterans Administration: Memorandum No. 2: Policy in Association of Veterans, Hospitals with Medical Schools. <https://www.va.gov/oaa/Archive/PolicyMemo2.pdf>
- 31) 1948-12 Likert R: Public Opinion Polls. Why did they fail? A leading authority assays their weaknesses and suggests some tested new techniques that would improve their accuracy. Scientific American <https://www.scientificamerican.com/article/public-opinion-polls/> (copy of article can be found in Scientific American.)

Dr. Likert developed his scale of attitudes to more simply define the general differences in attitudes of any given population using a scale that though arbitrary, had to show internal consistency. The scaling method demonstrated in the original paper a value in revealing general differences shown by different groups towards any subject with which they have dealings ; thus revealing their tendencies only towards a particular response and not any specific measured result. Controversy surrounds the attempt to use statistical means to give more understanding to Likert scale data.

The controversy involves the use of parametric analysis for ordinal data. As described by Likert originally, the numerical scale that is used in association with the arbitrary numbers of his scale of attitudes allows for the scale to be internally consistent. The scale also should appear to be based on equal seeming differences so when applied to a random population the validity is not placed in question. It is because of this number scale that parametric data can easily be used and which then raises the concern if you should apply parametric analysis to a number set obtained through ordinal means.

Jamieson *et al.* (2004) reiterates that mean and mode should be used as a 'measure of central tendency' instead of mean and standard deviations as the later are inappropriate for ordinal data. There are non-parametric test that should be used simply because to use parametric analysis the data must be of interval or ratio level. Pell (2005) offers a different point that non-parametric analysis can be used given the 'assumptions are clearly stated and the data is of the appropriate size and shape.' He remarks that this analysis can provide useful insight but that caution should be exercised before arriving at statistical conclusions.

Although sound data cannot honestly be obtained from parametric analysis of ordinal data, it is agreed in the literature that meaningful results and trends can be obtained and that even a combination of the two means may be used to greater results. --Author unknown to Dr. Andrus--

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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*  
**Prevention:** *Active Immunization:* Vaccines



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Holden Caulfield: "You ought to go to a boy's school sometime. Try it sometime," I said. "It's full of phonies, and all you do is study so that you can learn enough to be smart to be able to buy a goddam Cadillac some day, and you have to keep making believe you give a damn if the football team loses, and all you do is talk about girls and liquor and sex all day, and everybody sticks together in these dirty little goddam cliques."

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...Those Kansas newspaper and political leaders who had bitterly denounced him in earlier years praised Ross for his stand against legislative mob rule: "By the firmness and courage of Senator Ross," it said, "the country was saved from calamity greater than war, while it consigned him to a political martyrdom, the most cruel in our history... Ross was the victim of a wild flame of intolerance which swept everything before it. He did his duty knowing that it meant his political death... It was a brave thing for Ross to do, but Ross did it. He acted for his conscience and with a lofty patriotism, regardless of what he knew must be the ruinous consequences to himself. He acted right."

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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*  
**Prevention:** *Active Immunization:* Vaccines

Gallantry in action. Intrepidity. Above and beyond call of duty. Risk of life. Selflessness. Exemplary action. Unwavering devotion. Conspicuous gallantry. Extraordinary heroism. The words enshrined with the Medal of Honor citations capture the best of what it means to be human.

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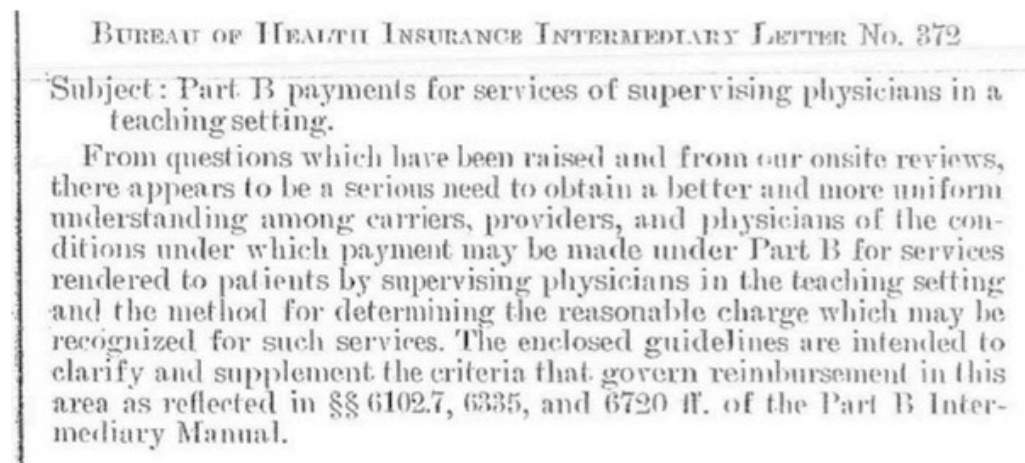
This paper records an attempt to assess the prophylactic value of immune gamma-globulin, prepared from the serum of recently vaccinated adults, in the protection of close contacts of smallpox in Madras. The results serve to confirm findings of a previous study made in Madras in 1953, and show that the incidence of smallpox in close contacts given immune gamma-globulin prophylactically was about a quarter of that in the control contacts who received no such passive immunization—a statistically significant difference. Because of the limited supply of immune gamma-globulin, is likely that its prophylactic use will be restricted to those especially at risk, for example, close unvaccinated family contacts, newborn infants and pregnant women.

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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*  
**Prevention:** *Active Immunization:* Vaccines

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- It therefore seems that antivaccinial gamma-globulin can be an effective agent in the prevention of smallpox where contacts are detected too late for vaccination to afford protection; it can never supplant vaccination, but is complementary and may succeed where vaccination must fail.
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- So, let us not be blind to our differences--but let us also direct attention to our common interests and to the means by which those differences can be resolved. And if we cannot end now our differences, at least we can help make the world safe for diversity. For, in the final analysis, our most basic common link is that we all inhabit this small planet. We all breathe the same air. We all cherish our children's future. And we are all mortal.
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[https://books.google.com/books?id=ZEAWAAAAIAAJ&pg=PA1685&lpg=PA1685&dq=irregularities+in+the+Salt+Lake+City,+Utah,+veterans%27+hospital+and+other+stations,+September+21,+1970&source=bl&ots=Rq38I\\_0fbD&sig=ACfU3U0Xt7RDQUZPuyLD6awYLD-RXu4NA&hl=en&sa=X&ved=2ahUKEwjL8-ysqr0AhWil2oFHZfTBxsQ6AF6BAGNEAM#v=onepage&q=irregularities%20in%20the%20Salt%20Lake%20City%2C%20Utah%2C%20veterans%20hospital%20and%20other%20stations%2C%20September%2021%2C%201970&f=false](https://books.google.com/books?id=ZEAWAAAAIAAJ&pg=PA1685&lpg=PA1685&dq=irregularities+in+the+Salt+Lake+City,+Utah,+veterans%27+hospital+and+other+stations,+September+21,+1970&source=bl&ots=Rq38I_0fbD&sig=ACfU3U0Xt7RDQUZPuyLD6awYLD-RXu4NA&hl=en&sa=X&ved=2ahUKEwjL8-ysqr0AhWil2oFHZfTBxsQ6AF6BAGNEAM#v=onepage&q=irregularities%20in%20the%20Salt%20Lake%20City%2C%20Utah%2C%20veterans%20hospital%20and%20other%20stations%2C%20September%2021%2C%201970&f=false)



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BUREAU OF HEALTH INSURANCE INTERMEDIARY LETTER No. 372

Subject: Part B payments for services of supervising physicians in a teaching setting.

From questions which have been raised and from our onsite reviews, there appears to be a serious need to obtain a better and more uniform understanding among carriers, providers, and physicians of the conditions under which payment may be made under Part B for services rendered to patients by supervising physicians in the teaching setting and the method for determining the reasonable charge which may be recognized for such services. The enclosed guidelines are intended to clarify and supplement the criteria that govern reimbursement in this area as reflected in §§ 6102.7, 6335, and 6720 ff. of the Part B Intermediary Manual.

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1873

Carriers are urged to review their present reimbursement practices in light of these guidelines and to take appropriate action as soon as possible to bring practices into conformity with the guidelines. The Part B Intermediary Manual will be revised to incorporate these clarifications and additions.

THOMAS M. TRENEY,  
Director, Bureau of Health Insurance.

PART B PAYMENTS FOR SERVICES OF SUPERVISING PHYSICIANS IN A  
TEACHING SETTING

A. Conditions which must be met for a teaching physician to be eligible  
for Part B reimbursement as an attending physician

The physician must be the patient's "attending physician." This means he must, as demonstrated by performance of the activities listed below, render sufficient personal and identifiable medical services to the Medicare beneficiary to exercise full, personal control over the management of the portion of the case for which a charge can be recognized; his services to the patient must be of the same character, in terms of the responsibilities to the patient that are assumed and fulfilled, as the services he renders to his other paying patients.

1. To be the "attending physician" for an entire period of hospital care, the teaching physician must as a minimum:

- (a) review the patient's history, the record of examinations and tests in the institution, and make frequent reviews of the patient's progress; and
- (b) personally examine the patient; and
- (c) confirm or revise the diagnosis and determine the course of treatment to be followed; and
- (d) either perform the physicians' services required by the patient or supervise the treatment so as to assure that appropriate services are provided by interns, residents, or others and that the care meets a proper quality level; and
- (e) be present and ready to perform any service performed by an attending physician in a nonteaching setting when a major surgical procedure or a complex or dangerous medical procedure is performed; for the physician to be an "attending physician" his presence as an attending physician must be necessary (not superfluous as where, for example, the resident performing the procedure is fully qualified to do so) from the medical standpoint; and
- (f) be recognized by the patient as his personal physician and be personally responsible for the continuity of the patient's care, at least throughout the period of hospitalization.

\* The term "physician" does not include any resident or intern of the hospital regardless of any other title by which he is designated or his position on the medical staff. For example, a senior resident, who is referred to as an "resident attending surgeon" or as "attending physician" would still be considered a resident since the senior year of the residency is essential to completion of the program.

1873

*Example.*—A supervising physician carried out all of the activities listed above for a surgical patient but (e). He was not present in the OR when the major surgery was performed because supervision of the 5th-year resident performing the operation was not required. A physician's charge would not be recognized for the surgical procedure because criterion (e) was not met. Therefore, the physician would not be an attending physician for the period of hospital care although he might meet the criteria listed in A.2. below and be held as the attending physician for a portion of the care provided.

Even if the supervising physician chose to be present in the OR, payment could not be made to him for the surgical procedure since his presence was not medically necessary and he could not, therefore, function as the attending physician in connection with the surgery. However, if he was scrubbed and acted as an assistant, payment could be made to him as a surgical assistant if such an assistant was needed and another resident or physician did not fill the role (see item A.2. below).

If the supervising physician was present at surgery, and the surgery was performed by a resident acting under his close supervision and instruction, he would not be the attending surgeon unless it were customary in the community for such services to be performed in a similar fashion to private patients who pay for services rendered by a private physician.

*Example.*—A group of physicians share the teaching and supervision of the house staff on a rotating basis. Each physician sees patients every third day as he makes rounds. No physician can be held to be one of these patient's attending physician for any portion of the hospital care although consultations and other services they personally perform for the patient might be covered.

2. A teaching physician may be held to be the attending physician for a portion of a patient's hospital stay; if the portion is a distinct segment of the patient's course of treatment (e.g., the pre-operative or post-operative period) and of sufficient duration to impose on the physician a substantial responsibility for the continuity of the patient's care; if the physician, as a minimum, performs all of the activities described above with respect to that portion of the stay; and if the physician is recognized as the patient's physician fully responsible for that part of the stay. If a teaching physician is not found to be the attending physician with respect to a portion of a patient's stay, he may not be reimbursed for any service provided to the patient for that portion of the stay unless it is an identifiable service that he personally rendered to the patient.

*Example.*—A physician carried out all of the activities listed above for a surgical patient until midway in the post-operative period, when the physician's teaching tour of duty ended. Since he was not responsible for the continuing care of the patient throughout the post-operative period, he cannot be reimbursed as the attending physician for that period.

3. Performance of the activities referred to above must be demonstrated, in part, by notes and orders in the patient's records that are either written by or countersigned by the supervising physician.

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**Treatment:** Passive Immunization: COVID-19 Convalescent Plasma and Antibodies and Antivirals

**Prevention:** Active Immunization: Vaccines



1874

4. The services of a teaching physician while visiting patients during grand rounds is basically teaching and does not contribute to an "attending" relationship with any of the patients visited.

5. An emergency room supervising physician may not customarily be considered to be the attending physician of patients cared for by the house staff. It is only through his direct personal involvement with a patient that a charge may be recognized under Part B. Such an involvement would necessarily include personal examination of the patient as well as direction of and responsibility for the treatment provided.

*B. Determining the amount payable under part B*

1. The amount paid for direct medical services rendered by the teaching physician should be related to only that discrete portion of the patient's care for which the physician exercised the pertinent responsibilities of an attending physician outlined in A.1. For example, if the patient's personal physician furnishes services before the hospital admission and after the discharge and the teaching physician becomes the attending physician only with respect to the inpatient care, the lesser extent of the teaching physician's service should be taken into account in recognizing a charge; otherwise the out-of-hospital service would be billed for and paid twice. Similarly, if surgery was performed and the teaching physician rendered identifiable personal service to the patient in the operating room, it is necessary to determine whether that physician performed services more nearly analogous to a consultant, an assistant at surgery (see first "Example" in part A), or as the "attending" surgeon in order to identify the appropriate reasonable charge. If the physician acted as the attending surgeon but did not render the pre- or post-surgical services generally performed by a private surgeon to a private patient, the difference in service should be reflected in the amount of reimbursement.

2. The following conditions should be taken into account in determining the "customary" charges of teaching physicians for services which they provide as attending physicians to Medicare beneficiaries.

(a) If the teaching physician has a substantial practice outside the teaching setting (i.e., more than half of the time spent in the practice of medicine is spent caring for people who were his patients before they were hospitalized or who were referred to him by physicians responsible for their care outside the hospital setting), his "customary" charges for services in the teaching setting will be related to the amounts he charges for similar services in his outside practice. Where the services performed in the teaching setting differ from those in the outside practice, reductions should be made for the lesser scope of services provided, time spent, visits or responsibility as an attending physician (not counting supervisory acts as time or visits).

(b) If the teaching physician does not have a substantial practice outside the teaching setting and the provider has established one or more schedules of charges which are collected for medical and surgical services furnished to a majority of non-Medicare teaching patients, his charges should be related to the provider's schedule of charges which are most frequently collected.

1875

*Example.*—A hospital with an approved teaching program receives payment for physicians' services rendered to 80 percent of its non-Medicare patients. Fifty percent are paid for by public assistance under a relatively low payment schedule; 20 percent are covered under a Blue Shield Plan with a somewhat higher fee schedule and the balances are covered under commercial plans. Since collections are made for a majority of patients and the most frequently used schedule of payment is the welfare schedule, the welfare schedule of charges should serve as the basis for determining the teaching physicians' customary charges for Medicare.

(c) Where neither the physician nor the provider has established charges for the physician's services which are in effect for non-Medicare patients, the carrier and intermediary must make the necessary charge and cost determination based on that portion of the physician's compensation which is for services to patients, determined pursuant to the regulations governing reimbursement for the services of provider-based physicians.

3. Where teaching physicians of a hospital, billing through a hospital or other organization, adopt a uniform schedule of charges for the purpose of billing under Part B for the services they provide as attending physicians in the teaching setting, carrier acceptance of the schedule for reimbursement purposes should be based on a finding that the schedule does not exceed the average of reasonable charges which would be determined if each physician were individually reimbursed his reasonable charge for the services involved.

4. In determining the number of visits which may be considered reasonable, e.g., in a course of treatment for which a global fee is not ordinarily charged, the total number of visits which would have been made to the patient in a nonteaching setting should be used as a guide; visits in excess of this number are presumed to be primarily for teaching purposes. Similarly, total reasonable charges for a course of treatment in the teaching setting should be compared with and should not exceed the charges that would be expected in nonteaching settings for similar services. Also, the charges billed for an hour of a teaching physician's services should not exceed the amount of fees the physician generally receives for an hour's work in caring for nonteaching patients.

5. Where payment is made under Part B on a reasonable charge basis, payment may not also be made on a cost basis to the hospital for the same service as a teaching service. Part A payments to the hospital should therefore not be based on the total compensation of the physician if that compensation is in part for patient care. The total compensation should be reduced by the portion paid for patient care in accordance with the applicable provisions of the principles of reimbursement for services of hospital-based physicians to arrive at the hospital cost portion. Allocation of compensation received between both parts of the program should be in accordance with how the physician's time is actually spent. If a physician's only compensation for services in a teaching setting are paid by the hospital and the agreement states that only the supervisory, and not patient care, services are compensated, it is necessary to look behind the words of the agreement by reviewing the physician's actual obligations and activities and deter-

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1876

mining whether the compensation level is reasonable for the supervisory and teaching services alone and insufficient to cover patient care services as well. The carrier and intermediary should make this finding jointly.

*Example.*—An employment agreement between a physician and the hospital states that he will be paid \$50,000 a year for administration, supervision and teaching. However, he spends one-half of his time in providing patient care. The carrier and intermediary determined that if his compensation were allocated solely to the time the physician spent in the performance of his hospital duties, it would yield an hourly rate of compensation about double the rate paid for similar work elsewhere in the area. Therefore, the carrier and intermediary concluded that only a portion of the compensation was for hospital activities and reimbursable under Part A. Since charges were not customarily billed for the medical services the physician provided, the remainder would serve as a basis for computing the physician's reasonable charges for patient care in accordance with B.2.b. above.

*Carrier responsibilities for claims review and verification*

1. The carrier is responsible for assuring that the bills being submitted were prepared with an understanding of the conditions governing payment for physicians' services in the teaching setting.

To help carry out this responsibility, carriers will not pay bills (SSA-1490 or SSA-1551) for services rendered in the teaching setting in any month after May 1969, unless:

(a) the chief of the department or service involved certifies on a form furnished by the carrier that each of the billed services for that month meets the pertinent requirements of A.1; or  
(b) the bill has been signed by the attending physician and he understands that he is certifying that he met the requirements for those services for which the claim is made.

2. The provision of personal and identifiable services must be substantiated by appropriate and adequate recordings entered personally by the physician in the hospital or, in the case of outpatient services, outpatient clinic chart. The carrier is expected as part of its responsibilities to make appropriate checks of patient records, examining admission, progress, and discharge notes to verify that services for which charges are billed meet the appropriate coverage criteria. If the carrier review shows that a significant portion of the services in the sample do not meet the criteria, appropriate steps should be taken to adjust the reimbursement.

3. Bills must indicate when services are furnished in the teaching setting, the name of the provider and attending physician involved, and the extent of the services provided as an attending physician. The services must be defined and quantified to avoid errors in applying the reasonable charge limitation—e.g., to avoid applying the reasonable charge for a global service where only the surgical procedure or another component service was provided as an attending physician.

4. The carrier will need to carry out the steps necessary to assure itself that these conditions set out in B.1. are met—for example, to assure itself that any schedule of charges proposed for the teaching setting is actually applied and collected.

*D. Who may bill*

Where the supervising physician is a member of a group which provides teaching services in a hospital, the Part B payment for services rendered (as attending physicians by the group may be billed for:

1. by the physician or a corporation, partnership, or other organization of physicians (including an association of teaching physicians organized for the purpose of billing for and distributing insurance monies and other payments received for professional services to patients) on form 1490;

2. by the hospital on form 1554 provided that the carrier has determined that the certification described in C.I.a. has been executed and complied with; and

3. if the services are performed by a physician who is a faculty member of a medical, osteopathic, or dental school, by the school on form 1490.

The individual physician's authorization is required to be on file in writing with the hospital or other organization to permit any of the above organizations to bill on his behalf. The organization must furnish to the Part B carrier the names of the physicians who have authorized the organization to bill on their behalf, and must agree to keep the carrier informed on a current basis of changes in membership in the group.

FEBRUARY 11, 1970

WASHINGTON, D.C., January 28, 1970.

To: Director, Investigation and Security Service.

From: K. F. Everett, Special Investigator.

Subject: Alleged Irregularities in Payroll Practices at V.A.H., Nashville, Tennessee.

Period of Investigation: December 4, 1969 to December 16, 1969 and January 5, 1970 to January 9, 1970.

*I. Authority*

Investigation was authorized by the Deputy Administrator on November 28, 1969.

*II. Matter investigated*

1. During a visit of an Internal Audit Service team at V.A.H., Nashville on another matter, information was developed that Radiology Service was establishing and maintaining Time and Attendance records for Residents and student Technicians who are not working for VA and that this appeared to be done for the purpose of generating funds for these persons or the Medical Center at the expense of appropriated funds.

2. Bobby Moore, Management Specialist, Internal Audit Service, assisted in the investigation.

*III. Narrative summary*

1. Hospital records show that on July 30, 1969, a contract was entered into between the Nashville V.A.H. and the Vanderbilt University to furnish five full-time Physicians from the Vanderbilt Department of Radiology to furnish radiology services to the V.A.H. through June 30, 1970 at a cost of \$117,000.00 per annum. The contract stipulates

61) 1969-09-03 Comptroller General of the United States: Report to the Committee on Finance United States Senate—Medicare payments for services of supervisory and teaching physicians at Cook County Hospital, Chicago, Illinois B-164031(4). National Library of Medicine, Bethesda 14, MD. W 275 AI3 U5m 1969  
[https://books.google.com/books?id=TVAsAAAAIAAJ&pg=PP5&lpg=PP5&dq=Medicare+Payments+for+Services+of+Supervisory+and+Teaching+Physicians+at+cook+county+hospital,+chicago,+illinois+B-164031\(4\)&source=bl&ots=sSRW70DaNv&sig=ACfU3U3Drb4swZ19p-w3yqjYX-pFjnegmA&hl=en&sa=X&ved=2ahUKEwjS5rOp86r0AhUDZc0KHZtaBDMQ6AF6BAGgEAM#v=onepage&q=Medicare%20Payments%20for%20Services%20of%20Supervisory%20and%20Teaching%20Physicians%20at%20cook%20county%20hospital%2C%20chicago%2C%20illinois%20B-164031\(4\)&f=false](https://books.google.com/books?id=TVAsAAAAIAAJ&pg=PP5&lpg=PP5&dq=Medicare+Payments+for+Services+of+Supervisory+and+Teaching+Physicians+at+cook+county+hospital,+chicago,+illinois+B-164031(4)&source=bl&ots=sSRW70DaNv&sig=ACfU3U3Drb4swZ19p-w3yqjYX-pFjnegmA&hl=en&sa=X&ved=2ahUKEwjS5rOp86r0AhUDZc0KHZtaBDMQ6AF6BAGgEAM#v=onepage&q=Medicare%20Payments%20for%20Services%20of%20Supervisory%20and%20Teaching%20Physicians%20at%20cook%20county%20hospital%2C%20chicago%2C%20illinois%20B-164031(4)&f=false)

Includes:

Response of Robert Freeark, M.D., Director, Associated Physicians of Cook County Hospital in a letter of July 3, 1969 to Mr. David Hanna, US GAO, pages 89-91 and Thomas Tierney, Director, Bureau of Health Insurance: Bureau of Health Insurance, Intermediary Letter No. 372.

Please see 20-2022-05-03 annotated Bibliographic Timeline References.pdf

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**Treatment:** Passive Immunization: COVID-19 Convalescent Plasma and Antibodies and Antivirals  
**Prevention:** Active Immunization: Vaccines

APPENDIX V  
Page 1

NOT RECORDED

COOK COUNTY HOSPITAL

GEORGE W. DUNNE, PRESIDENT  
BOARD OF COUNTY COMMISSIONERS

1825 WEST HARRISON STREET  
CHICAGO, ILLINOIS 60612

ROBERT J. FREEBARK, M.D.  
HOSPITAL DIRECTOR

WILLIAM H. HARVEY, COMMISSIONER  
HOSPITAL CHAIRMAN

PHONE AREA CODE 312 - 833-8000

FRED A. HERTWIG  
SUPERINTENDENT

July 3, 1969

Mr. David Hanna  
United States General Accounting Office  
610 South Canal Street  
Chicago, Illinois

Dear Mr. Hanna:

This will acknowledge my recent meeting with you and the opportunity it provided to review the rough draft of a proposed report by the General Accounting Office. Other than the minor corrections which you have agreed to make, I would also ask that you make two major additions.

One of the issues which the study raises is the extent to which attending physicians are providing supervision and direction to internes and residents. While I would agree that in many instances this supervision and direction is poorly documented in the medical record, this does not mean that it was not given. In many private hospitals, the only notation in a hospital chart to indicate that a physician visited a patient or performed a procedure, is that which appears in the nurses notes. We simply do not have enough nurses to provide this documentation and it is not realistic to expect this to be done by the physicians. I believe the vast majority of "undocumented services" were so categorized because neither a doctor's or a nurse's note records a visit.

I believe Recommendations #31 and #36 of the report of the Joint Commission on Accreditation of Hospitals (February 1968) should be included in your report. These statements and the fact that our internship and residency training programs are fully approved by the Council on Medical Education of the American Medical Association, is ample evidence that attending physicians are providing supervision and direction to our house staff. There is no doubt in my mind that patient care in a "Teaching Hospital" (one that conducts approved residency and interne training programs) is under greater scrutiny and better supervised than in hospitals without these programs.

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**Prevention:** Active Immunization: Vaccines

APPENDIX V  
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Mr. David Hanna

2.

July 3, 1969

These statements by the Joint Commission are pertinent to a thorough understanding of conditions at the hospital. In part, they constitute an explanation of why documentation of services rendered is so difficult.

My second request would be to ask that you include in your report my opinion as to the basis for compensation for salaried physicians at Cook County Hospital. This is in part a matter of semantics and has led to considerable misunderstanding. The concept that salaried physicians are not paid for patient care, but for their administrative and supervisory duties is predicated on the fact that over 50 percent of our salaried staff carry an extraordinary administrative and educational work load. An estimated 50%-70% of these salaried physicians are expected to supervise a large number of medical and non-medical personnel in activities not directly related to the care of the individual patient. (e.g., there are only two salaried positions for general surgery. These two men are administratively responsible for the assignment and education of 72 attending physicians, 62 general surgical residents, and an average of 30 internes and 42 medical students. This personnel changes regularly on the five general surgical wards that have a total bed capacity of over 300 patients. In addition, one of the two full time surgeons is also the Director of the Blood

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Bank, which has 23 technical persons in its employ.)

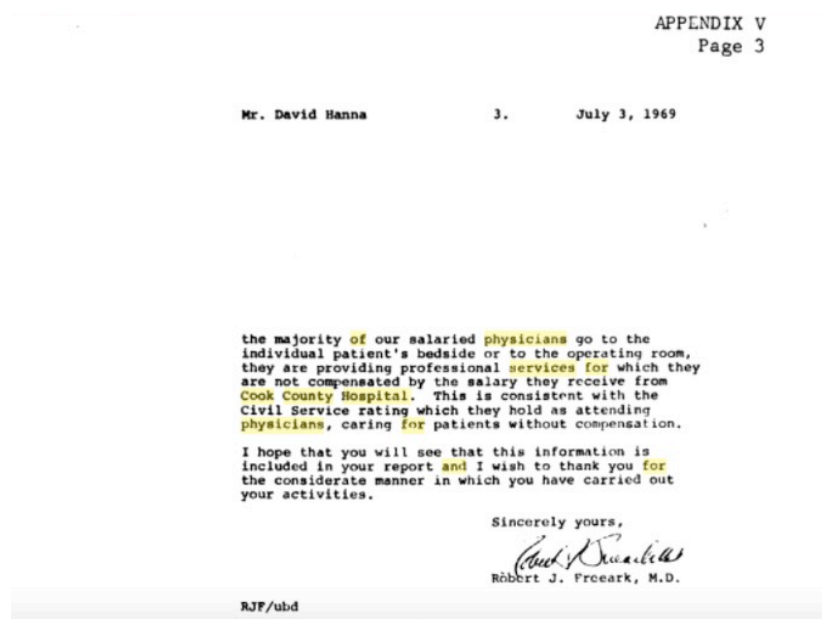
Furthermore, at the present time, the salary paid to over 60 percent of our full time staff represents only a portion (estimate 60%-70%) of their total professional income. In addition, this salary is approximately two-thirds that paid to physicians in comparable positions in hospitals in this geographic area. Based on the extraordinary administrative and formal educational responsibilities and the concept of a partial salary for a portion of their time, I am of the opinion that when

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**Prevention:** *Active Immunization:* Vaccines





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- 62) 1970 Anderson SG, Skegg J: The international standard for anti-smallpox serum. Bull. Wld Hlth Org 1970; 42: 515-523.  
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2427467/pdf/bullwho00215-0018.pdf>
- 63) 1970-02-11 Comptroller General of the United States: Regarding the GAO report of alleged overpayment to The Associated Physicians of the Cook County Hospital, B-164031(4)  
<https://www.gao.gov/assets/b-164031%284%29-089860.pdf>
- 64) 1973-04-28 U.S. Department of Health, Education, and Welfare, Public Health Service: FINAL REPORT of the Tuskegee Syphilis Study Ad Hoc Advisory Panel.  
<https://biotech.law.lsu.edu/cphl/history/reports/tuskegee/complete%20report.pdf>
- 65) 1974-06-15 Bernstein C, Woodward b: *All the President's Men*. New York: Simon & Schuster, 1974. [https://en.wikipedia.org/wiki/All\\_the\\_President%27s\\_Men](https://en.wikipedia.org/wiki/All_the_President%27s_Men)
- 66) 1977 Dallin A: Communism. The World Book Encyclopedia, Ci-Cz, Volume 4, Field Enterprises Educational Corporation, Chicago, 1977. P 724b-727.

**Why Communism?** The spread of Communism is usually thought of in terms of force and revolution. However, millions of persons have freely chosen to become Communists or to vote for them.

Communism has different appeals for different individuals and groups. Its main attraction for some is its claim to provide simple answers and solutions in difficult situations. Some persons join the party to avoid being outsiders, and to feel they are part of a meaningful group. Others join to ride the "wave of the future." They believe that Communist victory is inevitable.

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The appeals of Communism seem to be strongest in countries where some of the following conditions exist. (1) There are huge differences in income and social position between the poor and rich, and the poor feel these differences. (2) Communism is the only effective movement fighting for change, reform, or revolution. (3) The existing government does not command the strong loyalty of the people, and its institutions do not stand up well under stress. (4) Many persons feel deprived and discriminated against socially and economically, and as national or racial groups. (5) Communists are not looked on as criminals or lunatics, but as one of several accepted types of revolutionaries.

- 67) 1978 Brandt AM: Racism and Research: The case of the Tuskegee syphilis study. The Hastings Center Report 1978; 8(6): 21-29.  
[https://dash.harvard.edu/bitstream/handle/1/3372911/Brandt\\_Racism.pdf?sequence=1&isAllowed=y](https://dash.harvard.edu/bitstream/handle/1/3372911/Brandt_Racism.pdf?sequence=1&isAllowed=y)
- 68) 1979-04-01 FEMA founded. <https://www.fema.gov/>
- 69) 1979-04-18 Office of the Secretary, The National Commission for the Protection of Human Subjects of Research. The Belmont Report: Ethical principles and guidelines for the protection of human subjects of research. <https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html>
- 70) 1980 38 U.S.C. § 5705: Protection of Morbidity and Mortality conferences from legal discovery. <https://www.law.cornell.edu/uscode/text/38/5705>
- 71) 1981-04 Busuttill RW, Davidson RK, Fine J, Tompkins RK: Effect of prophylactic antibiotics in acute nonperforated Appendicitis – A prospective, randomized, double-blind clinical study. Ann Surg, Oct 1981; 194 (4): 502-509.  
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1345331/pdf/annsurg00212-0140.pdf>

Table 9. Postoperative Infections

	Number	Per Cent
Group I (Placebo)	6/45	13.3
Group II (cefamandole preop)	1/46	2.2
Group III (cefamandole and carbenicillin preop)	0/45	0

***This one study was extremely influential in the discontinuation of all placebo antibiotic studies. Subsequently all studies have been comparison studies between the new antibiotic with established antibiotics.***

- 72) 1986-06 Hyslop JW, Maull KI: Natural history of the retained surgical sponge. South Med J 1986 Jun; 75(6): 657-660. <https://pubmed.ncbi.nlm.nih.gov/7089613/>

- 73) 1982-06-24 U.S. Supreme Court: *Nixon v. Fitzgerald*, 457 U.S. 731 (1982), No. 79-1738, Argued November 30, 1981, Decided June 24, 1982.  
<https://supreme.justia.com/cases/federal/us/457/731/>

2. Petitioner, as a former President of the United States, is entitled to absolute immunity from damages liability predicated on his official acts. Pp. [457 U. S. 744-758](#).

(a) Although there is no blanket recognition of absolute immunity for all federal executive officials from liability for civil damages resulting from constitutional violations, certain officials -- such as judges and prosecutors -- because of the special nature of their responsibilities, require absolute exemption from liability. *Cf. Butz v. Economou*, [438 U. S. 478](#). Determination of the immunity of particular officials is guided by the Constitution, federal statutes, history, and public policy. Pp. [457 U. S. 744-748](#).

(b) The President's absolute immunity is a functionally mandated incident of his unique office, rooted in the constitutional tradition of the separation of powers and supported by the Nation's history. Because of the singular importance of the President's duties, diversion of his energies by concern with private lawsuits would raise unique risks to the effective functioning of government. While the separation of powers doctrine does not bar every exercise of jurisdiction over the President, a court, before exercising jurisdiction, must balance the constitutional weight of the interest to be served against the dangers of intrusion on the authority and functions of the Executive Branch. The exercise of jurisdiction is not warranted in the case of merely private suits for damages based on a President's official acts. Pp. [457 U. S. 748-754](#).

(c) The President's absolute immunity extends to all acts within the "outer perimeter" of his duties of office. Pp. [457 U. S. 755-757](#).

(d) A rule of absolute immunity for the President does not leave the Nation without sufficient protection against his misconduct. There remains the constitutional remedy of impeachment, as well as the deterrent effects of constant scrutiny by the press and vigilant oversight by Congress. Other incentives to avoid misconduct may include a desire to

Page [457 U. S. 733](#)

earn reelection, the need to maintain prestige as an element of Presidential influence, and a President's traditional concern for his historical stature. Pp. [457 U. S. 757-758](#).

- 74) 1983-05 Williams GR: Presidential Address: A history of appendicitis with anecdotes illustrating its importance. *Ann Surg* 1983 May; 197 (5): 495-506.

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1353017/pdf/annsurg00135-0007a.pdf>

(This citation is listed regarding page 504 in which the "teaching at the bedside" is epitomized by Dr. William Halsted (father of American Surgery) and Dr. William Osler (father of American Internal Medicine) weighing in on the appendicitis of Dr. Harvey Cushing (father of American Neurosurgery):

On September 9, 1987, Dr. Harvey Cushing, then a resident in Surgery at The Johns Hopkins Hospital, operated on a patient with a ruptured appendix. The patient died ten days later of peritonitis. This experience must have increased his apprehension when, on Sunday, September 26, 1897, Cushing experienced abdominal pain and carefully recorded the development of his own episode of acute appendicitis (Fig. 14). At 9:00 am the following morning, he was seen in consultation by Drs. Halsted and Osler who did not advise operation. At 2:00 pm on the same day, he was taken to the operating room where Dr. Halstead removed his appendix. A somewhat complicated recovery followed (fig. 15).

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75) 1985-11-28 Anderson RM, May RM: Vaccination and herd immunity to infectious diseases. *Nature* 1985; 318: 323-329. <https://www.nature.com/articles/318323a0.pdf>

76) 1986-08 Condon RE: Type III Error. *Arch Surg.* 1986;121(8):877-878.  
doi:10.1001/archsurg.1986.01400080019002  
<https://jamanetwork.com/journals/jamasurgery/article-abstract/591890>

Type I and type II errors are the two classic pitfalls in statistical analysis: finding a difference when there is none (type I) and failure to find a true difference (type II). **There is, in addition, another important error that regularly appears in scientific journals. This error, the type III error,<sup>1</sup> occurs whenever the conclusions drawn are not supported by the data presented. In recent years, type III errors have been increasing in prevalence.** Some illustrations drawn from recently published articles should serve to define my point. I have deliberately omitted citation of sources because my intent is to illustrate, not embarrass.

77) 1987 Cohen SN: Chapter 37: Immunization-Passive Immunization. *Basic & Clinical Immunology*, 6.<sup>th</sup> Edition. Stites DP, Stobo JD, Wells JV (eds), Norwalk, CT/Los Altos, CA: Appleton & Lange, 1987. Pages 669-673.

78) 1987-11-12 Trump DJ with Tony Schwartz: *TRUMP The Art of the Deal*. New York: Random House, 1987. <http://www.randomhousebooks.com/books/180675/>

Please note that the words “sorry” or “apologize” are not mentioned even once in this book.

79) 1990-04 Mullis KB: The unusual origin of the Polymerase Chain Reaction. A surprisingly simple method for making unlimited copies—during a moonlit drive through the mountains of California. <https://cs.brown.edu/courses/csci1810/resources/pcr%20origin.pdf>

80) 1992 Chard T: Review: Pregnancy tests: a review. *Human reproduction* 1992; 7 (5): 701-710. <https://academic.oup.com/humrep/article-abstract/7/5/701/631514?redirectedFrom=fulltext>

81) 1993 U.S. Institute of Medicine: *Veterans at Risk—The Health Effects of Mustard Gas and Lewisite*. Institute of Medicine (US) Committee on the Survey of the Health Effects of Mustard Gas and Lewisite. Constance M Pechura and David P Rall., eds. (Washington, D.C.: National Academies Press, 1993). <https://www.ncbi.nlm.nih.gov/books/NBK236070/> and <https://www.nap.edu/catalog/2058/veterans-at-risk-the-health-effects-of-mustard-gas-and>

82) 1993-05 Stark A: What’s the matter with business ethics? *Harvard Business Review*, May-June 1993. <https://hbr.org/1993/05/whats-the-matter-with-business-ethics>

And yet, I suspect that **the field of business ethics is largely irrelevant for most managers.** It’s not that they are hostile to the *idea* of business ethics. Recent surveys suggest that over three-quarters of America’s major corporations are actively trying to build ethics into their organizations. Managers would welcome

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concrete assistance with primarily two kinds of ethical challenges: first, identifying ethical courses of action in difficult gray-area situations (the kind that Harvard Business School Lecturer Joseph L. Badaracco, Jr. has described as “not issues of right versus wrong,” but “conflicts of right versus right”); and, second, navigating those situations where the right course is clear, but real-world competitive and institutional pressures lead even well-intentioned managers astray.

Henning PJ: When money gets in the way of corporate ethics. The New York Times, DealBook/Business & Policy, April 17, 2017.  
<https://www.nytimes.com/2017/04/17/business/dealbook/when-money-gets-in-the-way-of-corporate-ethics.html>

83) 1993-06-03 Dingell JD: Shattuck Lecture – Misconduct in Medical Research. N Engl J Med 1993 June 3; 328(22): 1610 – 1615.  
<https://www.nejm.org/doi/pdf/10.1056/NEJM199306033282207?articleTools=true>

84) 1993-07 Allen JB: Possessed.  
<https://archive.org/details/possessedtruesto00alle/page/n5/mode/2up>

85) 1995 Casadevall A, Scharff MD: Return to the past: the case for antibody-based therapies in infectious disease. Clin Infect Dis 1995; 21(1): 150-161.  
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7197598/pdf/21-1-150.pdf>

86) 1995 Mudd R: Last secrets of the Axis. <https://www.youtube.com/watch?v=d5ARbOVpFqc>

87) 1995-01-04: Meyer HS: *Gordon’s Guide to the Surgical Morbidity and Mortality Conference*. JAMA 1995; 273(1): 86-87. <https://jamanetwork.com/journals/jama/article-abstract/385539>

Gordon advocates inclusiveness and honesty about complications—“An untoward event contributing to morbidity or mortality is a complication whether it is expected, anticipated, or not,” and no type is exempt from presentation. He asserts that the familiarity a trainee gains at the M and M meeting with complications and their management is crucial to professional surgical development. He wishes training programs would resurrect the surgical notebook and the complications notebook, and the departments would devote real resources to M and M, including hiring an M and M secretary. ...

88) 1995-11 Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER), U.S. Food and Drug Administration: Guidance for Industry, Content and Format of Investigational New Drug Applications (INDs) for Phase 1 Studies of Drugs, Including Well-Characterized, Therapeutic, Biotechnology-derived Products. <https://www.fda.gov/media/72057/download>

89) 1996 Internet Archive: About the Internet Archive—a 501 (c)(3) non-profit building a digital library of Internet sites and other cultural artifacts in digital form. 300 Funston Ave,

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San Francisco, CA 94118 <https://archive.org/> (Throughout this bibliography, the Wayback Machine of the Internet Archive has been used to identify earlier overwritten documents within the same URL.). <https://archive.org/web/>

- 90) 1996 Thall PF, Simon RM, Estey EH: New statistical strategy for monitoring safety and efficacy in single-arm clinical trials.

<http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.989.470&rep=rep1&type=pdf>

- 91) 1996-08-30 Fauci AS: Letter to C.Everett Koop on his 80<sup>th</sup> birthday.

<https://profiles.nlm.nih.gov/spotlight/qq/catalog/nlm:nlmuid-101584930X417-doc>

...When people heard that I was a close friend of yours, they often asked me what it was like to know you and how impressed they were that you were a very unpredictable individual. I responded very confidently that, in fact contrary to their impressions, you were one of most predictable individuals that I had ever met. All one had to do was be insightful enough to figure out what the correct approach would be under unusually trying circumstances. Once you have that figured out, then Chick Koop is the most predictable person in the world because he always seems to do what is the most correct, honorable, and appropriate thing for the health of the Nation. This is your legacy and it is something for which you should be truly proud.

- 92) 1997 Shuster E: Fifty years later: The significance of the Nuremberg Code. N Engl J Med 1997; 337 (20): 1436-1440.

<https://www.nejm.org/doi/pdf/10.1056/NEJM199711133372006?articleTools=true>

- 93) 1997 Raffensburger J: Cook County Hospital. Encyclopedia of Chicago Cook County Hospital; *The Old Lady on Harrison Street: Cook County Hospital, 1833-1995*.

Raffensburger JG, Boshes, eds. *International Healthcare Ethics, vol 3, 1997*.

<http://www.encyclopedia.chicagohistory.org/pages/336.html>

- 94) 1997 Fisher JT: Dr. America. The Lives of Thomas A. Dooley 1927 - 1961. Amherst: University of Massachusetts Press, 1997. While Thomas Dooley, M.D. will always be a controversial, self-proclaimed, self-promoting figure in American history, his founding of his more than 20 clinics (MEDICO) in Southeast Asia after the conclusion of the French Indochina war was acclaimed at the time and their concept would be foundational in the establishment of Medecins Sans Frontieres (Doctors without borders).

<https://muse.jhu.edu/article/4109>

- 95) 1997 Foley, John S.J. Peace Prayer. <https://songstranslation.com/john-foley/peace-prayer/>

<https://www.youtube.com/watch?v=4vVICXJt0Y4>

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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*  
**Prevention:** *Active Immunization:* Vaccines



Lyrics: Beautiful adaptation of the Prayer of Saint Francis of Assisi Peace Prayer --  
Music and Lyric John Foley, SJ

1... Lord make me a means of Your Peace  
Where there's hatred grown  
Let me sow Your love  
Where there's injury Lord  
Let forgiveness be my sword  
Lord make me a means of Your Peace  
2... Lord make me a means of Your Peace  
When there's sadness here  
Let me sow Your joy  
When the darkness nears  
May Your light dispel our fears  
Lord make me a means of Your Peace  
3... Lord grant me to seek and to share  
Less to be consoled  
Than to help console  
Less be understood  
Than to understand Your good  
Lord make me a means of Your Peace  
4... Lord grant me to seek and to share  
To forgive in thee  
You've forgiven me  
For to die in thee  
Is eternal life to me  
Lord make me a means of Your Peace

96) 1997-05-16 Clinton WJ: Remarks by the President in apology for study done in Tuskegee.  
THE WHITE HOUSE, Office of the Press Secretary.

<https://clintonwhitehouse4.archives.gov/New/Remarks/Fri/19970516-898.html>

97) 1997-10-21 Cohen JJ: Statement of the AAMC on DHHS Inspector General "PATH" audits presented to the Subcommittee on Labor, Health and Human Services, Education and Related Agencies of the Committee on Appropriations, United States Senate.

<https://www.aamc.org/media/15286/download?attachment>

98) 1997-10-21 Cohen JJ: Statement of the Association of American Medical Colleges on DHHS Inspector General "Path" Audits presented to the subcommittee on Labor, Health and Human Services, Education and Related Agencies of the Committee on Appropriations, United States Senate. <https://www.aamc.org/media/15286/download?attachment> This very important AAMC response is regards to the PATH audits based on compliance with IL-372.

99) 1997-12 Feinstein AR, Horwitz RI: Problems in the "Evidence" of "Evidence-based medicine." Am J Med 1997 Dec; 103 (6): 529-535.

<https://www.sciencedirect.com/science/article/abs/pii/S0002934397002441>

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## Abstract

The proposed practice of “evidence-based medicine,” which calls for careful clinical judgment in evaluating the “best available evidence,” should be differentiated from the special collection of data regarded as suitable evidence. Although the proposed practice does not seem new, the new collection of “best available” information has major constraints for the care of individual patients.

Derived almost exclusively from randomized trials and meta-analyses, the data do not include many types of treatments or patients seen in clinical practice; and the results show comparative efficacy of treatment for an “average” randomized patient, not for pertinent subgroups formed by such cogent clinical features as severity of symptoms, illness, co-morbidity, and other clinical nuances. The intention-to-treat analyses do not reflect important post-randomization events leading to altered treatment; and the results seldom provide suitable background data when therapy is given prophylactically rather than remedially, or when therapeutic advantages are equivocal. Randomized trial information is also seldom available for issues in etiology, diagnosis, and prognosis, and for clinical decisions that depend on pathophysiologic changes, psychosocial factors and support, personal preferences of patients, and strategies for giving comfort and reassurance.

The laudable goal of making clinical decisions based on evidence can be impaired by the restricted quality and scope of what is collected as “best available evidence.” The authoritative aura given to the collection, however, may lead to major abuses that produce inappropriate guidelines or doctrinaire dogmas for clinical practice.

- 100)** 1998-07 United States General Accounting Office: Report to the Chairman, Subcommittee of Health, Committee on Ways and Means, House of Representatives: MEDICARE—concerns with Physicians at Teaching Hospitals (PATH) Audits, GAO/HEHS 98-174 <https://www.gao.gov/assets/hehs-98-174.pdf>
- 101)** 1998-08-12 36 U.S. Code 302 – National motto: “In God we trust” is the national motto. PL-105-225, Aug. 12, 1998, 112 Stat. 1263; PL 107-293, 3(a), Nov 13, 2002, 116 Stat 2060. <https://www.law.cornell.edu/uscode/text/36/302>
- 102)** 1999-11-22 Office of Inspector General, U.S. Department of Veterans: Combined Assessment Program review: Edward Hines, Jr. VA Hospital, Hines, IL. Report No.99-00173-18, Date: November 22, 1999. Appendix IV, pages 43-61 are documentation of my oversight responsibilities as Chief of Surgery, Edward Hines, Jr. VAH 1996 – 2002. [which VACO cannot misplace as they have my Official Professional File (OPF) of between April 1982 through August 2016] <https://www.va.gov/oig/cap/99-00173-18.pdf> **Please note that on pages 43-44 is: October 14, 1999....Charles H. Andrus, M.D., F.A.C.S., Chief, Surgical Service—the Office of Inspector General in Report No. 99-00173-18 of November 22, 1999 failed to do what is stated on the face page of the document: FULLY-REDACTED ELECTRONIC COPY FOR PUBLIC RELEASE**

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**Prevention:** *Active Immunization:* Vaccines

- 103) 1999-12-10 Andrus CH: Interviewed by the U.S. Department of Veterans Affairs, Veterans Health Administration 1999 Under Secretary for Health Commission for the position of Under Secretary for Health, Veterans Health Administration.
- 104) 2000 Institute of Medicine (US) Committee on Quality of Health Care in America; Kohn LT, Corrigan JM, Donaldson MS, editors. To Err is Human: Building a Safer Health System. Washington (DC): National Academies Press (US); 2000.  
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- 105) 2000-01 Kirkeby L, Rasmussen TT, Reinholdt J, Kilian M: Immunoglobulins in nasal secretions of healthy humans: Structural integrity of secretory immunoglobulin A1 (IgA1) and occurrence of neutralizing antibodies to IgA1 proteases of nasal bacteria. Clin Diagn Lab Immunol 2000; 7: 31-39  
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- 106) 2000-01 Axelrod DA, Dorr Goold S: Maintaining trust in the surgeon-patient relationship: *Challenges for the New Millenium*. Arch Surg 2000; 135 (1) : 55 – 61.  
<https://jamanetwork.com/journals/jamasurgery/fullarticle/390488>
- 107) 2001-02 Auerbach AD, Davis RB, Phillips RS: Physician views on caring for hospitalized patients and the hospitalist model of inpatient care. JGIM 2011 Feb; 16 : 116 - 119 . [https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1495177/pdf/jgi\\_91154.pdf](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1495177/pdf/jgi_91154.pdf)
- 108) 2001-03 La Vaque TJ, Rossiter T: The ethical use of placebo controls in clinical research: Appl Psychophysiol Biofeedback 2001; 26 (1): 23 – 37.  
<https://link.springer.com/article/10.1023/A:1009563504319>
- 109) 2001-03-31 Hoots WK, Abrams C, Tankersley D: The Food and Drug Administration's perspective on plasma safety. <https://pubmed.ncbi.nlm.nih.gov/11441417/>
- 110) 2001-04-01 Andrus CH, Johnson K, Pierce E, Romito PJ, Hartel P, Berrios-Guccione S, Best W: Finance modeling in the delivery of medical care in tertiary-care hospitals in the Department of Veterans Affairs. J Surgical Research.2001 Apr 01; 96 (2): 152 – 157.  
[https://www.journalofsurgicalresearch.com/article/S0022-4804\(99\)95728-1/pdf](https://www.journalofsurgicalresearch.com/article/S0022-4804(99)95728-1/pdf)
- 111) 2001-05 U.S. Department of Health and Human Services, Food and Drug Administration, , Center for Drug Evaluation and Research (CDER), Center for Biologics Evaluation and Research (CBER): Guidance for Industry—E 10 Choice of Control Group and Related Issues in Clinical Trials. May 2001. <https://www.fda.gov/media/71349/download> (E10 Choice of control group and related issues in clinical trials, content current as of 8/24/2018. <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/e10-choice-control-group-and-related-issues-clinical-trials> )

112) 2001-05-15 VA Office of Public and Intergovernmental Affairs: Under Secretary for Health announces intent to resign. <https://www.va.gov/opa/pressrel/pressrelease.cfm?id=269>

113) 2001-06 Meltzer D: Hospitalists and the doctor-patient relationship. J Legal Stud 2001 Jun; 30 (2): 589 – 606. <https://pubmed.ncbi.nlm.nih.gov/12647747/> for abstract and for full paper: <https://www.jstor.org/stable/10.1086/339294>

114) 2001-07-01 Richelson JT: When Secrets Crash. Air Force Magazine. <https://www.airforcemag.com/article/0701crash/>

On Sept. 24, 1959, Thomas L. Crull was flying a newly arrived U-2C, Article 360, on a local flight, heading back to Atsugi after setting an altitude record. As the U-2's fuel ran low, the airplane suffered a flameout—forcing Crull to make a dead-stick, wheels-up landing at the Fujisawa glider strip, 10 miles from Atsugi. Crull emerged unhurt, but his airplane overran the runway and slid onto the grass.

Letting the airplane simply sit there unguarded was not an option. A short time later several security personnel, apparently wearing loud Hawaiian shirts and packing large revolvers, showed up and began to order the growing crowd at gunpoint to stand away from the secret aircraft. The tactic proved counterproductive as it only led to extensive publicity about the crash landing. Eventually, the airplane would be packed off to the US, repaired, and returned to service with Det. B in Turkey.

From there, that airplane would make its final flight. It came on May 1, 1960, and its pilot was Francis Gary Powers. Powers was flying high over Sverdlovsk, USSR, when his U-2 came under attack by some 14 surface-to-air missiles. The U-2 broke apart, but Powers parachuted down safely and was captured, given a trial, and sentenced to 10 years in a labor camp. He was freed in 1962 in an exchange for the Soviet spy, Rudolf Abel.

115) 2001-09-20 Emanuel EJ, Miller FG: The ethics of placebo-controlled trials – A middle ground. N Engl J Med 2001; 345: 915-919. <https://www.nejm.org/doi/pdf/10.1056/NEJM200109203451211?articleTools=true>

116) 2001-10-25 Garthwaite TL: Resident Supervision. VHA Handbook 1400.1, U.S. Department of Veterans Affairs, Veterans Health Administration, Transmittal Sheet, October 25, 2001 and 5. **Rescissions:** This VHA Handbook rescinds VHA Handbook 1400.1, March 21, 2000.

[https://www.va.gov/oaa/1400\\_1hk\\_Oct2001.doc](https://www.va.gov/oaa/1400_1hk_Oct2001.doc) returns the VA official website which states: **Sorry – we can't find that page.** Using the Wayback Machine, for 2004-10-28: [http://web.archive.org/web/20041028182959/https://www.va.gov/oaa/1400\\_1hk\\_Oct2001.doc](http://web.archive.org/web/20041028182959/https://www.va.gov/oaa/1400_1hk_Oct2001.doc) which states on pages 8 – 9:

(3) **Level 3.** The staff practitioner is immediately available in the facility – campus for direct resident supervision according to local policy as approved by the Network Academic Affiliations Officer. The service chief is responsible for periodically reviewing cases done under Level 3 supervision to ensure that such supervision is appropriate.

Using the Wayback Machine another version of the Level 3 Supervision (now Level D) is identified: In VHA Handbook of July 27, 2005 signed by Jonathan B. Perlin, M.D.

[https://web.archive.org/web/20051107072236/http://www.va.gov:80/OAA/1400\\_1hk\\_July27\\_05.doc](https://web.archive.org/web/20051107072236/http://www.va.gov:80/OAA/1400_1hk_July27_05.doc) (Recission of the previous version of May 3, 2004 which cannot be found):

4. **Level D: Attending in OR Suite, Immediately Available.** The supervising practitioner is physically present in the operative or procedural suite and immediately available for resident supervision or consultation as needed.

Using the only other “hit” on the Wayback Machine of December 21, 2016,

[http://web.archive.org/web/20161221045318/http://www.va.gov/oaa/1400\\_1hk\\_Oct2001.doc](http://web.archive.org/web/20161221045318/http://www.va.gov/oaa/1400_1hk_Oct2001.doc) VHA 1400.1 has been removed completely and in its place is the website of the U.S. Department of Veterans Affairs which states: “Page Not Found.” ***De facto*, the U.S. DVA, VHA misdirected official government documentation which is tantamount to destruction of evidence used in the trial of Andrus v VA, U.S. Court of Appeals for the Federal Circuit, docket # 03-3162.**

117) 2001-11-17 FBI: History: Amerithrax or Anthrax Investigation.

<https://www.fbi.gov/history/famous-cases/amerithrax-or-anthrax-investigation>

118) 2002 Kennedy C: *Profiles in Courage for our time*. Woodward, Bob: Gerald R. Ford.

New York: Hyperion, 2002. Pages 293-318. <https://www.jfklibrary.org/about-us/news-and-press/press-releases/profiles-in-courage-for-our-time>

Each of these men displayed a rare form of courage, sacrificing their own future, and that of their families, to do what they believed was right for the country. Their example comes down to us across the years, their stories are part of our history, and their spirit lives on. The John F. Kennedy Profile in Courage Award is presented annually to an elected official who carries on this tradition. When we created the award in 1990, some doubted we would be able to find politicians worthy of the honor. They were wrong. This book tells the stories of men and women at all levels of government, in all parts of our country, across the political spectrum, who have all stood fast for the ideals of America.

119) 2002 Eye witness to history: “Julius Caesar Crosses the Rubicon, 49 BC,” EyeWitness to History. <http://www.eyewitnesstohistory.com/caesar.htm>

120) 2002 Proteintech Group: (Copyright 2002-2022) Polyclonal vs. monoclonal antibodies.

Proteintech <https://www.ptglab.com/news/blog/polyclonal-vs-monoclonal-antibodies/>

121) 2002-04-25 Breman JG, Henderson DA: Diagnosis and management of smallpox. N

Engl J Med, April 25, 2002; 346 (17): 1300-1308.

<https://www.nejm.org/doi/pdf/10.1056/NEJMra020025?articleTools=true>

122) 2002-08-28 Watts J: Japan guilty of germ warfare against thousands of Chinese—Tokyo judges rule that second world war atrocities did take place but reject claims for compensation. The Guardian For200years

<https://www.theguardian.com/world/2002/aug/28/artsandhumanities.japan>

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**Prevention:** *Active Immunization:* Vaccines



- 123) 2003-01-03 FDA, Center for Biologics Evaluation and Research (CBER): Guidance for Industry—Recommendations for deferral of donors and quarantine and retrieval of blood and blood products in recent recipients of smallpox vaccine (Vaccinia Virus) and certain contacts of smallpox vaccine recipients. <https://www.federalregister.gov/documents/2003/01/03/03-113/guidance-for-industry-recommendations-for-deferral-of-donors-and-quarantine-and-retrieval-of-blood>
- 124) 2003 Wei A, Juneja S: Bone marrow immunohistology of plasma cell neoplasms. J Clin Pathol 2003; 56: 406-411. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1769975/pdf/jcp05600406.pdf>
- 125) 2003 Yu WC, Hui DSC, Chan-Yeung M: Antiviral agents and corticosteroids in the treatment of severe acute respiratory syndrome (SARS). (Editorials in the British Medical Journal). [www.thoraxjnl.com](http://www.thoraxjnl.com) , <https://thorax.bmj.com/content/thoraxjnl/59/8/643.full.pdf>
- 126) 2003-01-16 Gawande AA; Studdert DM, Orav EJ, Brennan TA, Zinner MJ: Risk factors for retained instruments and sponges after surgery. N Engl J Med 2003 Jan 16; 348(3): 229-235. <https://www.nejm.org/doi/pdf/10.1056/NEJMsa021721?articleTools=true>
- 127) 2003-03-03 **Andrus CH:** Andrus v VA. U.S. Court of Appeals, Federal Circuit. Case 03-3162. Oral arguments, March 3, 2004. The U.S. Court of Appeals, Federal Circuit's ruling in the case of Andrus v. VA was to fail to rule, *per curiam*. <https://dockets.justia.com/docket/circuit-courts/cafc/03-3162>  
  
Andrus CH: To Care for Him Who Shall Have Borne the Battle, And for his Widow, and his Orphan—*A. Lincoln*. Registered in the Copyright Office of the U.S. Library of Congress, USA, April 5, 2004, ©TXu1-173-542, (Revised with cover letter, table of contents, and correspondence with the Office of the Counsel to the President: August 24, 2004, ©TXu1-196-220). A compilation of documents related to U.S. Court of Appeals for the Federal Circuit Case 03-3162 *Andrus v. VA*, VA OIG Inspector General Reports regarding VHA Part-Time Physician Time and Attendance and alleged inappropriate transfers of VA patients, and correspondence with the Office of the Counsel to the President. [Was submitted and has been included in the unpublished BioEthics collection of the Joseph and Rose Kennedy Institute of Ethics, Georgetown University, National Reference Center for Bioethics Literature supported by the U.S. National Library of Medicine. Notified on Sept. 13, 2004 that the title and table of contents of this manuscript are to be added to the library's "ETHX on the Web" at <http://bioethics.georgetown.edu> in September/October, 2004]
- 128) 2003-03-28 CDC—MMWR: Cardiac adverse events following smallpox vaccination – United States, 2003. Morbidity and Mortality Weekly Report, March 28, 2003; 52 (12); 248-250. <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5212a2.htm> Subsequent MMWR July 11, 2003: <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5227a4.htm> Subsequent MMWR August 29, 2003: <https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5234a4.htm>

- 129) 2003-04-23 U.S. Department of Veterans Affairs, VA Office of Inspector General: Audit of the Veterans Health Administration's Part-time Physician Time and Attendance. Report no. 02-01339-85, April 23, 2003. <https://www.va.gov/oig/52/reports/2003/VAOIG-02-01339-85.pdf>
- 130) 2003-05-08 Griffin RJ: Statement of the Honorable Richard J. Griffin, Inspector General, Department of Veterans Affairs Hearing on Past and Present Efforts to Identify and Eliminate Fraud, Waste, Abuse, and Mismanagement in Programs Administered by the Department of Veterans Affairs before the Committee on Veterans Affairs [www.va.gov/OCA/testimony/hvac/03my08IG.asp](http://www.va.gov/OCA/testimony/hvac/03my08IG.asp)
- 131) 2003-05-07 Andrus CH, Kleinman BS, Mozdierz GJ, Sinacore JM, Garthwaite TL: Mortality outcomes and attending surgeon presence at the time of operation. Presentation before the Association for Surgical Education (ASE). <https://web.archive.org/web/20040414163722/http://www.surgicaleducation.com/pdf/mortoutcomesattending.pdf>

**From slide 10:**

**The coefficient of determination ( $r^2$ ) was 0.77 which indicates 77% of the variance of O/E ratios was attributable to the % of Attending Surgeons presence (and 23% was not)**

On the next day, May 8, 2003, Richard Griffin, Inspector General, U.S. Department of Veterans Affairs testified before the Veterans Affairs Committee of the U.S. House of Representatives regarding "efforts to identify and eliminate fraud, waste, abuse, and mismanagement in programs administered by the Department of Veterans Affairs." His testimony was a summary of a previous month's report from the Office of Inspector General entitled: *Audit of Veterans Health Administration's part-time physician time and attendance*. The audit which was discussed in the previous reference.

[https://www.va.gov/oig/pubs/statements/VAOIG-Testimony\\_5-8-03\\_US\\_House\\_of\\_Representatives\\_Cmte\\_on\\_Veterans\\_Affairs.pdf](https://www.va.gov/oig/pubs/statements/VAOIG-Testimony_5-8-03_US_House_of_Representatives_Cmte_on_Veterans_Affairs.pdf)

- 132) 2003-05-12 Huang Y: The SARS epidemic and its aftermath in China: A political Perspective. Institute of Medicine (US) Forum on Microbial Threats; Knobler S, Mahmoud A, Lemon S, *et al*, editors. Washington (DC): National Academies Press (US); 2004. <https://www.ncbi.nlm.nih.gov/books/NBK92479/>

This paper is adapted from the Politics of China's SARS Crisis. *Harvard Asia Quarterly* (Autumn 2003). An earlier version of the article appeared in "Dangerous Secrets: SARS and China's Healthcare System," Roundtable before the Congression-Executive Commission on China, May 12, 2003, [www.cecc.gov](http://www.cecc.gov)

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133) 2003-05-12 Takada A, Kawaoka: Antibody-dependent enhancement of viral infection: molecular mechanisms and *in vivo* implications. Rev Med Virol 2003; 13: 387-398.  
<https://onlinelibrary.wiley.com/doi/full/10.1111/vox.12386>

134) 2003-06-01 Andrus CH, Villasenor EG, Kettelle JB, Roth R, Sweeney AM, Matolo NM: "To err is human": Uniformly reporting medical errors and near misses, a naïve, costly, and misdirected goal. J Am Col Surg 2003 June 1; 196 (6): 911-918.  
<https://pubmed.ncbi.nlm.nih.gov/12788428/>

Andrus CH, Villasenor EG, Kettelle JB, Roth R, Sweeney AM, Matolo NM: "To Err is Human": Uniformly Reporting Medical Errors and Near Misses: A Naïve, Costly and Misdirected Goal. J Am Coll Surg 196(6): 911-918, June 2003. [Was requested on January 29, 2004 by Doris Goldstein, M.L.S., M.A., Director, National Reference Center for Bioethics Literature for inclusion in the collection of published bioethical articles of the Joseph and Rose Kennedy Institute of Ethics, Georgetown University, National Reference Center for Bioethics Literature supported by the U.S. National Library of Medicine. Added to the library's "ETHX on the Web" at <http://bioethics.georgetown.edu> in August, 2004.]

135) 2003-08 Orlander JD, Fincke BG: Morbidity and Mortality Conference—A Survey of Academic Internal Medicine Departments. J Gen Intern Med 2003; 18(8): 656-658.  
[https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1494908/pdf/jgi\\_20824.pdf](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1494908/pdf/jgi_20824.pdf)

136) 2003-11-10 Andrus CH: Ethical issues in "medicine" that touched our family. U.S. Copyright Office, TXu001145557 <https://cocatalog.loc.gov/cgi-bin/Pwebrecon.cgi?v1=2&ti=1,2&Search%5FArg=Andrus%20Charles%20H&Search%5FCode=NALL&CNT=25&PID=711zUFRXvEu8UUeMe4EnculiAYnRa&SEQ=20220305181742&SID=2>

137) 2004-01-11 Barry JM: The site of origin of the 1918 influenza pandemic and its public health implications. Journal of Translational Medicine – BioMed Central.  
[www.ncbi.nlm.nih.gov/pmc/articles/PMC340389/pdf/1479-5876-2-3.pdf](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC340389/pdf/1479-5876-2-3.pdf)

138) 2004-03-03 Andrus CH: *Andrus v VA*: Oral arguments regarding Resident Supervision in the OR before a three judge panel of the U.S. Court of Appeals for the Federal Circuit. Oral arguments, March 3, 2004. The U.S. Court of Appeals, Federal Circuit's ruling in the case of *Andrus v. VA* was to fail to rule, *per curiam*. <https://dockets.justia.com/docket/circuit-courts/cafc/03-3162>

139) 2004-03-16 Andrus CH: Correspondence from the US Office of Special Counsel in *Andrus v. VA* and allegations of obstruction of justice / compiled by Charles H. Andrus. U.S. Copyright Office, TXu001165703. <https://cocatalog.loc.gov/cgi-bin/Pwebrecon.cgi?v1=11&ti=1,11&Search%5FArg=Andrus%20charles%20h&Search%5FCode=NALL&CNT=25&PID=y78dIAKyanVeyTb6Zs2tE9R4etD9sLF&SEQ=20210515161739&SID=5>

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- 140) 2004-04-05 **Andrus CH**: To care for him who shall have borne the battle and for his widow and his orphan. U.S. Copyright Office, TXu001173542. <https://cocatalog.loc.gov/cgi-bin/Pwebrecon.cgi?v1=12&ti=1,12&Search%5FArg=Andrus%20charles%20h&Search%5FCode=NALL&CNT=25&PID=XsOYHcY7XWApNoXfDBOnuAs5Sn75IS&SEQ=20210515162652&SID=9>
- 141) 2004-04-14 Guo JP, Petric M, Campbell W, McGeer PL: SARS corona virus peptides recognized by antibodies in the sera of convalescent cases. *Virology* 2004; 324: 251-256. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7125913/pdf/main.pdf>
- 142) 2004-04-05: U.S. Department of Veterans Affairs, Office of Public and Intergovernmental Affairs: VA Under Secretary for Health Resigns. <https://www.va.gov/opa/pressrel/pressrelease.cfm?id=742>
- 143) 2004-04-08 Sawyer D: Fighting For Care, ABC News Primetime Live. <https://vimeo.com/116428212> (now in the Internet Archive: <https://web.archive.org/web/20211122005236/https://vimeo.com/116428212> ).

After OIG Inspector Griffin's testimony on May 8, 2003, ABC *Primetime* investigated for an entire year and on April 8, 2004, aired *Fighting for Care* narrated by Diane Sawyer. 2004-04-08 Sawyer D: *Fighting For Care*, ABC News Primetime Live. <https://vimeo.com/116428212> (now in the Internet Archive: <https://web.archive.org/web/20211122005236/https://vimeo.com/116428212> ) This episode was removed from the ABC Archives possibly because ABC to hidden cameras into the Cleveland and Waco VAMCs. 2004 George Polk Award for "Television Reporting: Diane Sawyer and Robbie Gordon, *ABC News PrimeTime Live*, for "*Fighting for Care*," which documented patient abuse and deplorable conditions in VA hospitals." (for investigative reporting excellence) <https://liu.edu/polk-awards/past-winners#2004>. When Tammy Shehari, the Associate Producer for the episode, spoke with me by phone in 3/2004, she asked me to estimate how many additional veterans had died due to unsupervised operations performed by Surgery Residents— I declined to guess because to do so would be wrong and a disservice to the Veteran patients and the men and women of Department of Veterans Affairs that do their duty faithfully for Veteran patients. (The interview ended shortly after my refusing to guess, and this was the only time ABC News spoke with me.)

Please note the reference above -- VHA USH, Robert Roswell, M.D. resigned three days prior to the airing of *Fighting for Care*. *Fighting for Care* contained within unauthorized hidden cameras in the Cleveland VAMC and the Waco VAMC. The VA spin was: ...Robert Roswell, who himself resigned in 2004 owing to problems with a multimillion-dollar computer system that the VHA had been testing in Florida. .... <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2690309/>

[https://web.archive.org/web/20040409151345/http://abcnews.go.com/sections/Primetime/Living/VA\\_Hospitals\\_040408-1.html](https://web.archive.org/web/20040409151345/http://abcnews.go.com/sections/Primetime/Living/VA_Hospitals_040408-1.html)

(Somewhere between Sept 1, 2004 and October 9, 2004, *Fighting for Care* was take off ABC News' Website when one uses the internet archive.—Charles Andrus, M.D., 3-20-2022)

Recently, there have been new stories of misdiagnosis, disastrous management and deficient care at some of the nation's 162 facilities.

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**Prevention:** *Active Immunization:* Vaccines

At a hospital near Cleveland, an ABCNEWS hidden-camera investigation found bathrooms filthy with what appeared to be human excrement. Supply cabinets were in disarray, with dirty linens from some patients mixed in with clean supplies, or left in hallways on gurneys.

At a neighboring facility, examining tables had dried blood and medications still on them. In several areas, open bio-hazardous waste cans were spilling over. *Primetime* obtained internal memos documenting that the equipment used to sterilize surgical instruments had broken down — causing surgical delays and possible infection risks.

With 130,000 young American men and women putting their lives at risk in Iraq today, these conditions are particularly relevant. While current soldiers are treated in military hospitals, when they leave the service and need treatment, many will seek care at Veterans Affairs (as the Veterans Administration is now known) hospitals.

"Once you come back to be a veteran, it's like a black hole, you know — nothing," former Army Sgt. Vanessa Turner told ABCNEWS.

Turner was stricken with a mysterious illness while on duty in Iraq this past year. She retired from the military on medical grounds, and when she reported to a VA hospital for treatment, doctors scheduled her for an appointment six months later.

#### **Not a Point of Pride**

Veterans who responded to a survey by the American Legion in 2003 said it took an average of seven months to get a first appointment at a VA hospital. In some hospitals, patients have waited as long as two years.

In 1999, Jack Christensen, a former army sergeant who served in the Korean War, was admitted to the VA hospital in Temple, Texas, with pneumonia, and ended up staying three years.

Christensen's wife, Pat, says the attitude of some of the practical nurses was shocking. Some of the patients were forced to beg for food and water, she says. Instead of helping her husband go to the bathroom, she said, "they would put a towel under his hips and tell him to use the towel."

Pat Christensen said her husband's condition worsened over several months — so badly that at one point he developed horrific bedsores and dangerous infections, and she says his doctors said they would have to amputate his legs.

Pat moved her husband to a private facility, where his infection healed and he underwent extensive physical therapy. She sued the VA, and then used the money to pay for private care for her husband. The VA denied liability but paid a settlement.

Dr. Jonathan Perlin, the deputy undersecretary for health, said the VA system has sophisticated quality control. But when he was shown ABCNEWS' hidden-camera video of hallways and supply closets in disarray, he said, "This is something we're not proud of."

#### **Fundamental Problems**

Critics have long charged that the VA system puts patients on a kind of assembly line, passing them from doctor to doctor.

There's also criticism of how the VA uses residents — doctors still training and not certified in their specialties.

Terry Soles served in the Navy during the Vietnam War. His wife, Denise, says he was one casualty of this practice. In 1998, he went to the VA hospital in Cleveland complaining of pain and diarrhea, and doctors removed small cancerous growths from his stomach and esophagus.

But as his symptoms persisted over the next two years, his wife says the VA gave him painful tests and repeatedly lost the results. His wife says Soles was seen by a parade of constantly rotating resident doctors, and there was little consistency in his care.

Once, Soles was prepped for surgery but before the operation the doctors who were present couldn't agree on what they were going to do, she said.

Before he got sick, the 6-foot Soles weighed more than 200 pounds. By the time his family finally decided to take him to a private hospital, he weighed 80 pounds. Some VA doctors thought his problem was psychosomatic.

When he could no longer recognize his own son, Soles was rushed to a private hospital. There, Soles learned he was "a total mass of cancer from his trachea to his renal bowel. And that there was nothing that could be done," his wife says. Terry Soles died three days later.

The VA's Perlin said the Soles story was tragic, but added: "However, that is not the experience of most of the veterans who come to us for care. ... We take care of 7 million veterans. While the majority of care is good, in a big system, bad things happen."

#### **Whose Fault?**

Critics charge that one of the big problems facing the VA is that too much money goes toward administration, at the cost of nursing and patient care.

Dean Billik, the former director of the VA in Charleston, S.C., is brought up as an example.

In 1996, he was denounced for allegedly spending about \$200,000 in taxpayer money to redecorate his office; \$1.5 million to renovate a nursing home unit that stayed empty for two years; and tens of thousands of dollars for a fish tank in the lobby — while there were budget shortfalls and staff cutbacks were contemplated.

Congress heard testimony claiming Billik was "blatant in his mismanagement," and an inspector general's report confirmed several of the numerous allegations against him.

But after everything was brought to light, Billik still got a bigger job: He was put in charge of the third-largest hospital system in the VA, encompassing eight cities, 295 acres of land and 83 buildings. And his salary immediately jumped about \$15,000.



*Primetime* obtained budget information on the central Texas VA system for Billik's six-year tenure at the top. It confirms that Billik cut spending \$2 million for the people in direct patient care — nurses aides and practical nurses.

Other documents obtained by *Primetime* show that \$129 million was spent on construction at three of six facilities in Temple, Texas.

One source says Billik spent \$1.8 million renovating a building at Temple for his own offices — after it had been renovated for patient care.

Furthermore, Nancy Kelsey, who was a nurse at one of the Temple facilities under Billik's supervision, says the way some of the staff treated patients was alarming. She says IVs ran out, patients were neglected and dressings weren't changed.

Melba Bell, whose husband, Ed, served in Korea, said the staff was often idle and it would often take hours to get help. Other families said that if patients or their families persisted in asking for help, some of the staff retaliated.

At one point, Bell's infection got so bad that the hospital used maggots to try to eat away the decay. That's not unusual treatment, but what happened afterward was.

"The dressing that they had on there was real poorly done," said Bell's granddaughter, Chesney Shirmer.

"Some of the maggots got out and they were in the bed with him, you know? He could feel them in the bed."

Ed Bell died of gangrene in the VA hospital in 2002.

#### **One More Problem**

When confronted with these details, Perlin said he shared the outrage and promised to look into fixing these things.

But there is one more problem. Many whistle-blowers and critics say if you try to expose the truth, VA managers don't want to hear it.

Charles Steinert, who worked for Billik in Charleston, says he felt pressure to leave after he complained about some of the building projects and how he was being treated by supervisors.

Nurse Melissa Craven, who also worked at the Charleston VA, says she suffered retribution for two years after she spoke out about some of her supervisors.

Perlin said it is easy for patients and their loved ones to lodge complaints about VA care. "That's important to us, because if there are concerns, we want to address them," he said.

But many patients and their loved ones told ABCNEWS that wasn't their experience — and even worse, many of the families are afraid to speak out.

"They're afraid to say what really goes on, because they're afraid any little benefits that they have are going to be taken away from them," said Denise Soles.

#### **Improvement Efforts**

The day after *Primetime* presented its findings to the VA's Perlin, he ordered inspections of the facilities *Primetime* investigated.

They found a number of problems at the Temple, Texas, VA, including poor hygiene, insufficient staffing and low satisfaction among patients and their families.

The VA announced it would bring in new supervisors, reassign some personnel, train others, and begin recruiting additional staff.

Inspectors who went to the VA in Cleveland said it was in good condition. However, after their visit, *Primetime* received phone calls from several sources saying that the hospital had advance warning of the so-called surprise inspection.

And to those patients who accuse the VA of assembly-line care — that patients go through a succession of doctors — a public relations officer for the VA said it tries to ensure continuity of care, but that may not always be possible.

As for Dean Billik, he has now retired. In a phone conversation on Wednesday, he said he disagreed with the VA inspectors, saying their report was "an opinion."

Billik said he relied on his staff to supervise nursing and recommend budgets, and if he had renovated some buildings that then were closed it was because he didn't possess 20/20 hindsight and made the best decisions at the time.

Rep. Ted Strickland, a member of the House Veterans Affairs Committee, called for the White House and Congress to approve enough money to ensure that veterans get the care they deserve.

It's a "situation that's crying out for change," the Ohio Democrat said after viewing *Primetime's* tapes.

Veterans and their families agree they deserve better. "They were good enough to go fight for their country," said Melba Bell. "They deserve to have the best treatment that they could get."

Denise Soles says that before her husband died he asked just one thing of her: to speak out.

She said Terry Soles told her, "If we can help one other veteran from going through the hell ... That's what we have to do." ■

*Some Internet resources for veterans:* **Gireports**, <http://www.gireports.com>; **Iraq War Veterans Organization**, <http://www.iraqwarveterans.org>; **American Legion**, <http://www.legion.org>; **National Gulf War Resource Center**, <http://www.ngwrc.org>

- 144) 2004-05-15 Christian MD, Poutanen SM, Loutfy MR, Muller MP, Low DE: Severe acute respiratory syndrome. *Emerging Infections*, CID 2004 May 15; 38: 1420 – 1427.  
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7107873/pdf/38-10-1420.pdf>
- 145) 2004-05-03 Perlin JB: Resident Supervision.  
[https://web.archive.org/web/200411041043461/http://www.va.gov/oaa/1400\\_1hb\\_May-3-04.doc](https://web.archive.org/web/200411041043461/http://www.va.gov/oaa/1400_1hb_May-3-04.doc)
- 146) 2004-08-24 **Andrus CH**: To care for him who shall have borne the battle, and for his widow, and his orphan. U.S. Copyright Office, TXu001196220.  
[https://cocatalog.loc.gov/cgi-bin/Pwebrecon.cgi?v1=10&ti=1,10&Search%5FArg=Andrus%20charles%20h&Search%5FCode=NALL&CNT=25&PID=fcPuXPdJ8uEW1DkNl\\_3NKsUujWeSj-d&SEQ=20210515161520&SID=4](https://cocatalog.loc.gov/cgi-bin/Pwebrecon.cgi?v1=10&ti=1,10&Search%5FArg=Andrus%20charles%20h&Search%5FCode=NALL&CNT=25&PID=fcPuXPdJ8uEW1DkNl_3NKsUujWeSj-d&SEQ=20210515161520&SID=4)
- 147) 2004-09-16 **Andrus CH**: “*Primum non nocere*” and practicing ethics in medicine in this era of “the bottom line.” U.S. Copyright Office, TXu001203831.  
[https://cocatalog.loc.gov/cgi-bin/Pwebrecon.cgi?v1=7&ti=1,7&Search%5FArg=Andrus%20charles%20h&Search%5FCode=NALL&CNT=25&PID=1oM\\_rZG-zbNmdQvAShIDo4LwK6mHQOn&SEQ=20210515160330&SID=2](https://cocatalog.loc.gov/cgi-bin/Pwebrecon.cgi?v1=7&ti=1,7&Search%5FArg=Andrus%20charles%20h&Search%5FCode=NALL&CNT=25&PID=1oM_rZG-zbNmdQvAShIDo4LwK6mHQOn&SEQ=20210515160330&SID=2)
- 148) 2004-10-07 **Andrus CH**: Rationing of medical care and the election of 2004. U.S. Copyright Office, TXu001192071. <https://cocatalog.loc.gov/cgi-bin/Pwebrecon.cgi?v1=8&ti=1,8&Search%5FArg=Andrus%20charles%20h&Search%5FCode=NALL&CNT=25&PID=4iZ1dm184qpLAbM4gtkZ6Lpi-K68-hK&SEQ=20210515160704&SID=3>

## Rationing of Medical Care and the Election of 2004

Summer 1999: VA OIG Combine Assessment Program;  
<https://www.va.gov/oig/cap/99-00173-18.pdf>

Dr. Thomas Garthwaite, VHA Undersecretary for Health, met at Dr. Garthwaite’s request with Dr. Andrus in Atlanta, GA at the AVAS on April 8 & 9, 2001. Three days later after having met with Dr. Andrus, Dr. Garthwaite announced his resignation (but would stay on until January 2002 as the USH) and the official published reason for his resignation was:

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But Thomas Garthwaite, who had been Kizer's deputy undersecretary, maintained the momentum of the reforms during his tenure as (initially acting) undersecretary between 1999 and 2002. **Garthwaite resigned over disagreements about policy direction with Anthony Principi, the first VA secretary appointed by the Bush administration** (page 22)

Oliver A: The Veterans Health Administration: An American Success Story? The Milbank Quarterly. 2007 Mar; 85(1): 5-35.

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2690309/>

It seemed as though a conjuncture of events very different from those that had opened the window for reform were conspiring against Kizer's leadership. To place Kizer's tenure in context, no undersecretary for health has ever been reconfirmed by the Senate for a second term, and Kizer is the only undersecretary ever to have been renominated by the White House, which indicates that he did still have the support of some senior politicians. Nonetheless, at the end of the nine-month extension of his contract, he resigned.

Leadership that commands great respect is probably quite rare in any large health care organization, and Kizer's departure could have been highly detrimental to the VHA. But Thomas Garthwaite, who had been Kizer's deputy undersecretary, maintained the momentum of the reforms during his tenure as (initially acting) undersecretary between 1999 and 2002. **Garthwaite resigned over disagreements about policy direction with Anthony Principi, the first VA secretary appointed by the Bush administration, and was replaced by Robert Roswell, who himself resigned in 2004 owing to problems with a multimillion-dollar computer system that the VHA had been testing in Florida.** From then until August 2006, Jonathan Perlin served as undersecretary. Even though it is inevitable that some staff will be dissatisfied with personal leadership styles and no undersecretary will be universally admired, my impression from those with whom I corresponded and interviewed is that the VHA has had at least three able leaders (i.e., Kizer, Garthwaite, and Perlin)

Veterans Health Administration: American Success Story? 23  
since the mid-1990s and that their impact on morale and performance, albeit impossible to isolate and quantify, is likely to have been positive.

149) 2004-11-30 Peiris JSM, Guan Y, Yeun KY: Severe acute respiratory syndrome. Nature Medicine Supplement 2004 December; 10(12):S88 – S97.

[https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7096017/pdf/41591\\_2004\\_Article\\_BFnm1143.pdf](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7096017/pdf/41591_2004_Article_BFnm1143.pdf)

150) 2004-12-23 Cheng Y, Wong R, Soo YOY, Lee CK, Ng MHL, Chan P, Wong KC, Leung CB, Cheng G: Use of convalescent plasma therapy in SARS patients in Hong Kong. Eur J

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Clin Microbiol Infect Dis 2005; 24: 44 – 46.

[https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7088355/pdf/10096\\_2004\\_Article\\_1271.pdf](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7088355/pdf/10096_2004_Article_1271.pdf)

- 151) 2005 Andrus CH: Chapter 3: The Dog Lab and Chapter 12-14: Discussion and Reflections. *Dear Mr. President...to care for him who shall have borne the battle....* Unpublished work. Appendix H: Andrus

- 152) 2005 Corazzini KN, Lekan-Rutledge D, Utley-smith Q, Piven ML, Colón-Emeric CS, Bailey D, Ammarell N, Anderson RA: “The Golden Rule”: Only a starting for quality care. NIH Public Access Author Manuscript, *Director* 2005; 14(1): 255-293.  
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1636677/pdf/nihms-8340.pdf>

- 153) 2005-04 Peel M: Human rights and medical ethics. J R Soc Med 2005 Apr; 98(4): 171-173. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1079446/pdf/00980171.pdf>

- 154) 2005-08-20 Andrus CH: Correspondence regarding the manuscript Mortality outcomes and attending surgeon presence at the time of operation. U.S. Copyright Office, TXu001262126 <https://cocatalog.loc.gov/cgi-bin/Pwebrecon.cgi?v1=5&ti=1,5&Search%5FArg=Andrus%20charles%20h&Search%5FCo de=NALL&CNT=25&PID=49mUgm0LoUN2xjhEZHaERAuUD2qzDv0&SEQ=20210515162031&SID=6>

- 155) 2005-09-20 Lai ST: Treatment of severe acute respiratory syndrome. Eur J Clin Microbiology Infect Disease 2005; 24: 583-591.  
[https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7088345/pdf/10096\\_2005\\_Article\\_4.pdf](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7088345/pdf/10096_2005_Article_4.pdf)

- 156) 2005-11 Itani KMF, DePalma RG, Schiffner T, Sanders KM, Change BK, Henderson WG, Khuri SF: Surgical resident supervision in the operating room and outcomes of care in Veterans Affairs hospitals. Am J Surg 2005; 190 (5): 725-731.  
[https://www.americanjournalofsurgery.com/article/S0002-9610\(05\)00638-0/fulltext](https://www.americanjournalofsurgery.com/article/S0002-9610(05)00638-0/fulltext)

**“Abstract Conclusions:** Between 1998 and 2004, the level of resident supervision in the OR did not affect clinical outcomes adversely for surgical patients in the VA teaching hospitals. (page 725)”

**Table 1** Levels of attending supervision in the operating room as defined throughout the years of study (page 726)

1998-2002 Level 3: attending not present, but available  
2002-2004 Level 3: attending not present in OR suite, immediately available  
2004 Level D: attending in OR suite, immediately available

The Abstract Conclusions of “not affect clinical outcomes adversely for surgical patients”, were **CONTRADICTED BY THE VA’S reported absolute criteria:**  
**Emergency case, 30-day mortality rate, and return to OR**

**Table 4** Intraoperative variables (page 729)

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Intraoperative variables.	Attend 3 (N = 39,577).	All other cases (N = 571,083).	<i>P</i> value
Emergency case	12.84% (5,080)	6.79% (38,785).	< .001

**Table 5** Unadjusted postoperative outcomes (page 730)

Outcome	Attend 3 (N = 39,577)	All other cases (N = 571,083)	<i>P</i> value
30-day mortality rate	2.66% (1,054)	2.34% (13,387)	< .001
30-day morbidity rate.	8.27% (3,274)	10.47% (59,805)	< .001
Return to OR.	10.24% (4,052)	8.19% (46,755)	< .001

- 157) 2005-12-02 **Andrus CH**: Addendum to correspondence regarding the manuscript: Mortality outcomes and attending surgeon presence at the time of operation. U.S. Copyright Office, TXu001274328 <https://cocatalog.loc.gov/cgi-bin/Pwebrecon.cgi?v1=4&ti=1,4&Search%5FArg=Andrus%20charles%20h&Search%5FCo de=NALL&CNT=25&PID=j6kpQfMyPdWq0VDjv-N11SdPUGFYx9f&SEQ=20210515162248&SID=7>
- 158) 2006-01 Fischer IV, BA: A summary of important documents in the field of research ethics. Schizophrenia Bulletin 2006; 32 (1): 69-80. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2632196/>
- 159) 2006-03 Offit PA: The Cutter incident: How America's first polio vaccine led to a growing vaccine crisis. J Royal Society of Medicine 2006 March; 99: 156-157. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1383764/pdf/0156.pdf>
- 160) 2006-03-12 Mushnick P: Don't trust those toothpaste ads. New York Post. Mushnick P: Don't trust those toothpaste ads. New York Post
- 161) 2006-03-15 **Andrus CH**: Correspondence regarding aberrancies in attending surgeon supervision of resident surgeons in the VA. U.S. Copyright Office, TXu001288808 [https://cocatalog.loc.gov/cgi-bin/Pwebrecon.cgi?v1=1&ti=1,1&Search%5FArg=Andrus%20charles%20h&Search%5FCo de=NALL&CNT=25&PID=t5aZ\\_WNrJwM2dwI9mTXmymaRAJ09FgP&SEQ=20210515162456&SID=8](https://cocatalog.loc.gov/cgi-bin/Pwebrecon.cgi?v1=1&ti=1,1&Search%5FArg=Andrus%20charles%20h&Search%5FCo de=NALL&CNT=25&PID=t5aZ_WNrJwM2dwI9mTXmymaRAJ09FgP&SEQ=20210515162456&SID=8)
- 162) 2006-07 Rohrich R: "See One, Do One, Teach One": An old adage with a new twist. Plastic and Reconstructive Surgery, Journal of the American Society of Plastic Surgeons 2006 July; 118(1): 257-258. [https://journals.lww.com/plasreconsurg/fulltext/2006/07000/See\\_One\\_Do\\_One\\_Teach\\_One\\_An\\_Old\\_Adage\\_with\\_a.45.aspx](https://journals.lww.com/plasreconsurg/fulltext/2006/07000/See_One_Do_One_Teach_One_An_Old_Adage_with_a.45.aspx)

The old adage in medicine, "see one, do one, teach one," has changed. It was thought to have served medicine, especially surgery, well over the last century of changes in medical care and medical education, especially when there was no specific or formalized medical training in this country. However, in the new era of American medical compliance (Health Insurance Portability and Accountability Act, patient safety concerns, and compliance oversight),<sup>1</sup> from our various



professional societies as well as at the state and federal levels, this adage needs to be looked at again and may actually have been detrimental to the patient and the physician's overall well-being.

The days are long gone of residents being unsupervised and teaching other residents on a daily basis. ...

- 163) 2006-10 Malik P: The perils of omission. Can J Cardiol 2006 Oct; 22 (12):1011.  
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2568961/pdf/cjc221011.pdf>
- 164) 2007 Golias Ch, Charalabopoulos A, Stagikas D, Charalabopoulos K, Batistatou A: The kinin system – bradykinin: biological effects and clinical implications. Multiple role of the kinin system – bradykinin. HIPPOKRATIA 2007; 11 (3): 124 – 128.  
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2658795/>
- 165) 2007 Hillyer CD, Silberstein LE, Ness PM, Anderson KC, Roback JD: *Blood Banking and Transfusion Medicine*, 2<sup>nd</sup> edition. Philadelphia: Churchill Livingstone, Elsevier Inc., 2007. Chapter 1, Pg 1 – 11. <https://jhu.pure.elsevier.com/en/publications/blood-banking-and-transfusion-medicine-6> By the end of 1943, the military was sent: 2.5 million packages of dried plasma and 125,000 units of albumin.
- 166) 2007-04-17: Saint Louis University v. Masonic Temple Association of St Louis. No. SC 88075. <https://caselaw.findlaw.com/mo-supreme-court/1195359.html>
- 167) 2007-10-01 Jack JL: 10 Things you didn't know about Stephen Breyer. U.S. News and World Report. <https://www.usnews.com/news/national/articles/2007/10/01/10-things-you-didnt-know-about-stephen-breyer>
- 168) 2007-10-31 CDC: U.S. Public Health Service Syphilis Study at Tuskegee.  
<https://web.archive.org/web/20071201193417/https://www.cdc.gov/tuskegee/timeline.htm>
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The past seven years have seen a great deal of turmoil in teaching hospitals across the country. Disruptive events in the teaching environment have included the PATH (Physicians at Teaching Hospitals) audits and the resulting expectation for documented faculty presence during procedures, and additional enhanced documentation requirements on faculty and residents. Both have affected the relationship between faculty and residents, and have had a significant impact on the operation of teaching services. A number of our teaching hospitals are safety net institutions, and they have felt tremendous financial pressure. As clinical burdens have increased, faculty time and energy for innovation has been limited. The majority of our teaching hospitals are feeling the burden of the growing uninsured population, the need to provide service to these patients and the escalating needs of the growing population of elderly in the United States. These and many other factors diverted the efforts of the educational community, and slowed the work of innovation in evaluation of physician competency.

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### Size of SARS-CoV-2

Since the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) was first identified in December of 2019, many infectious disease specialists, as well as researchers for almost every avenue of medicine, have been investigating how this virus spreads to and infects human beings, the wide range of severe health effects it can cause and ultimately what drugs will be able to effectively kill this virus safely.

In addition to mechanistic information, researchers have also evaluated the size and content characteristics of the SARS-CoV-2 particles. Upon analysis of negative-stained SARS-CoV-2 articles by electron microscopy, different researchers have had varying results, but the diameter of the virus has been found to range between 50 nm to 140 nm.

In addition to measuring the spherical size of the virus particle, it has also been confirmed that the length of the size tumors surrounding the outermost surface of SARS-CoV-2 can vary in length from 9 to 12 nm.

### Why does size matter?

Around the world, health officials have agreed that wearing masks can prevent the spread of the virus between individuals. While this may be true, certain masks are considered much more effective at minimizing the risk of exposure, particularly N95 masks.

Whilst N95 masks from different producers may have slightly different specifications, the protective capabilities offered by N95 masks are largely attributed to the masks' obligation to remove at least 95% of all particles with an average diameter of 300 nm or less.

The size of a virus particle largely determines how individuals can protect themselves and those around them from acquiring SARS-CoV-2. Knowing the size of a single virus particle can also allow researchers and healthcare providers to infer the amount of virus individuals are exposed to through different routes.

For example, respiratory droplets are typically 5-10 micrometers (µm) in length; therefore, it can be inferred that an individual who ingests, inhales, or is otherwise exposed to SARS-CoV-2

positive respiratory droplets can be exposed to hundreds or thousands of virus particles which increases the probability of infection.

Respiratory droplets can be transmitted through coughing, sneezing, contact with contaminated surfaces, or even through inhaled aerosols; therefore, each individual must take adequate steps to reduce their exposure to these particles by wearing masks and practicing safe social distance measures.

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Alexander Pope, poet of the Enlightenment, lent a famous line from his 1711 treatise *An Essay on Criticism* to the US Institutes of Medicine's report on patient safety: **To Err is Human.**<sup>1</sup> The remainder of the line, “to forgive divine,” would have further reinforced the report's message. Those who made mistakes should neither be blamed nor punished, it argues, instead, to look at the system. ...

... Elsewhere in his essay, **Pope stresses the many human factors that lead to bad outcomes: overconfidence, tunnel vision, bias, prejudice and inconsistency,** among others, and exhorts us to combine “good nature and good sense” in our judgment. ...

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[https://www.luc.edu/wolf,kettle/The\\_legend.shtml](https://www.luc.edu/wolf,kettle/The_legend.shtml)  

Many years ago, in the Basque country of Spain, there lived a prosperous and generous family who, after feeding family, retainers, and soldiers, had enough to feed even the wild animals. To commemorate this act of generosity, a carving of two wolves eating at a cauldron was placed over the lintel of the family's home in Loyola, Spain.

Many centuries later, St. Ignatius of Loyola would be born into this family and would go on to establish the Jesuit order and change the world. Today, we celebrate this act of generosity, which has become the heraldic shield of the Loyola family, the symbol of this University, and a fitting tribute to our donors, whose generosity makes your education possible at Loyola.
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[www.historyofvaccines.org](http://www.historyofvaccines.org) <https://www.historyofvaccines.org/content/blog/polio-and-swimming-pools-historical-connections>
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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*  
**Prevention:** *Active Immunization:* Vaccines

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Also: Epstein NE: Morbidity and mortality conferences: Their educational role and why we should be there. Surgical Neurology International S377-S388.  
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3520073/pdf/SNI-3-377.pdf>

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[https://www.va.gov/OPTOMETRY/docs/VHA\\_Handbook\\_1400-01\\_Resident\\_Supervision\\_12-19-2012.pdf](https://www.va.gov/OPTOMETRY/docs/VHA_Handbook_1400-01_Resident_Supervision_12-19-2012.pdf)

5. **RECISSIONS.** VHA Handbook 1400.1, Resident Supervision, dated July 27, 2005 is rescinded..... (page 1). *[Please note that when one searches for VHA Handbook 1400.1, Resident Supervision, dated July 27, 2005, one is redirected to VHA Handbook 1400.01. Using the Wayback Machine and the previous URL for VHA 1400:*  
[http://web.archive.org/web/20161221045318/https://www.va.gov/oa/1400\\_1hk\\_Oct2001.doc](http://web.archive.org/web/20161221045318/https://www.va.gov/oa/1400_1hk_Oct2001.doc) ,  
*one can find the 2001 version in the 2004 of the Internet Archive captures. There are no other captures of this URL in the Wayback Machine except December 21, 2016 which brings up the VA Website which states: "Page Not Found."*

**4. Level D: Attending in OR Suite, Immediately Available.** The supervising practitioner is physically present in the operative or procedural suite and able to provide direct supervision or consultation without delay as needed. (page 9)

- 206) 2013 World Health Organization: Vaccine Safety Basics learning manual.  
[https://www.who.int/vaccine\\_safety/initiative/tech\\_support/Vaccine-safety-E-course-manual.pdf](https://www.who.int/vaccine_safety/initiative/tech_support/Vaccine-safety-E-course-manual.pdf) Part 2: [https://www.who.int/vaccine\\_safety/initiative/tech\\_support/Part-2.pdf](https://www.who.int/vaccine_safety/initiative/tech_support/Part-2.pdf)

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- 208) 2013-02-13 U.S. National Library of Medicine: C. Everett Koop, The C. Everett Koop Papers. <https://profiles.nlm.nih.gov/spotlight/qq/feature/biographical-overview>

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<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2253576/pdf/0980396.pdf>

"He was a real icon before he even became surgeon general," said Anthony **Fauci**, MD, director of the National Institute of Allergy and Infectious Diseases and a longtime friend and colleague of Koop.

Koop considered retiring after a trailblazing career that resulted in surgical techniques still used today to save tiny newborns. Yet being tapped to serve as surgeon general at age 64

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**Treatment:** Passive Immunization: COVID-19 Convalescent Plasma and Antibodies and Antivirals  
**Prevention:** Active Immunization: Vaccines

excited Koop, who as he approached his 91st birthday, credited his longevity to both genetics and working in a field he adores.

“I’ve never had a job where I didn’t like to get up in the morning and go to it, and that’s, I think, unusual,” he said from his office at the Koop Institute at Dartmouth. “I told that to a group of medical students a couple of years ago and they looked at me like I was out of my mind.”

Known for his powerful speaking voice and trademark beard that have led some to describe him as resembling an Old Testament prophet, Koop likely was such an effective surgeon general because he truly cared about the people he was working to protect. And he doesn’t mince words or tiptoe around what some might think of as political land mines.

“He’s a completely transparent, honest, tell-it-like-it-is kind of person,” said **Fauci**, once Koop’s personal physician and a confidant at the time the surgeon general was working on his controversial AIDS report. “He’s just not afraid of anybody.”

“This is a man who, above all else, is willing to communicate his convictions with courage when it’s the right thing to do,” said Timothy Johnson, MD, MPH, medical editor for ABC News and coauthor with Koop of *Let’s Talk: An Honest Conversation on Critical Issues: Abortion, Euthanasia, AIDS, Health Care*. “He’s always willing to dialogue and listen to the other side. I think that’s a great strength.”

... Koop said. “I did a lot of things that I thought were public health, and that stood me in good stead for decisions I had to make. It wasn’t nearly the leap that some people think it was or that you might think it is, to go from being a surgeon of individual patients who had a surgical problem to 347 million people, which is what the population was when I went to Washington.”

Just before a group of public health luminaries headed to a dessert table to cap off Koop’s 90th birthday celebration in Washington, DC, the guest of honor gave an impassioned speech about the need for health care reform. Echoed in a December 2006 *Journal* editorial,<sup>6</sup> Koop outlined 3 core principles for reform: the fundamental right of all people to have the highest standard of health care, that disparities are “absolutely unacceptable”<sup>1</sup> and at odds with the right to health, and that public, private, and health-related agencies need to make disease prevention and health treatment a priority.

Former Surgeon General Richard Carmona, who served from 2002 to 2006, said Koop brought the office “to a new standard” and was effective because he “stepped up and took risks and did the right thing.” Koop said his success can be attributed to a combination of factors.

“I look back on those days, and some things I accomplished because I was naïve. Some things I accomplished because I was furious and I wasn’t going to let that stand in my way,” Koop said with a smile. “Other things I accomplished by what I call moral suasion . . . and by that I mean having an explanation for what you want to do that transmits the passion you feel for it, the rightness of what you want to do and why it is good for the recipients to have somebody advocate for them because nobody else will.”

Those who know Koop well, including Johnson of ABC News, know that the man who hopes to be remembered as “the health conscience of the nation”<sup>2</sup> will work as long as he’s able to improve the public’s health. “He studies. He knows what he’s talking about,” Johnson said from his office in New York. “He knows how to say things that will capture your attention.”

1990-10-08 Koop, CE: Speech: ‘Exasperation on both sides of the stethoscope’ American College of Surgeons, San Francisco, CA, October 8, 1990.

<https://profiles.nlm.nih.gov/spotlight/qq/catalog.nlm:nlmuid-101584930X1005-doc>

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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*  
**Prevention:** *Active Immunization:* Vaccines

THEREFORE, MY MESSAGE TO THE DOCTORS IN AMERICA IS: WHEN YOU ARE DEALING WITH A PATIENT YOU ARE REPRESENTING ALL OF AMERICAN MEDICINE, YOU ARE REPRESENTING AMERICAN HEALTH CARE.

WE HAVE MUCH TO DO, BUT LET'S NOT LOSE OUR POSITIVE ENERGY.

THE MESSAGE WE HAVE TO SHARE WITH OURSELVES AND WITH THE AMERICAN PEOPLE IS A POSITIVE ONE. WE DON'T NEED THE PAST TENSE,...NOSTALGIA ABOUT THE GOOD OLD DAYS; NOR DO WE NEED SOME FUTURISTIC MANIFESTO PROMISING WHAT WE INTEND TO DO.

WE NEED CLEAR AND PERSISTENT AFFIRMATION OF THE MANY GOOD THINGS WE DO, DAY IN AND DAY OUT, TO MAKE OUR SYSTEM OF MEDICINE—ONCE WE TAKE THINGS IN HAND—POTENTIALLY THE BEST IN THE WORLD.

I HAVE NEVER REGRETED GOING INTO MEDICINE. I'D DO IT AGAIN TOMORROW. AND I TELL THAT TO ANY YOUNGSTERS WHO ARE CONSIDERING IT.

OURS IS A CALLING. IT IS NOT A BUSINESS. WE COULD HAVE MADE MONEY DOING OTHER THINGS.

WE CHOOSE MEDICINE —SURGERY—BECAUSE IT COMBINED A QUEST FOR KNOWLEDGE WITH A WAY TO SERVE, TO SAVE LIVES, AND TO ALLEVIATE SUFFERING.

WE HAVE TO CONVINCE THE PUBLIC WE STILL MEAN IT; IF WE DO, WE'LL GET WHAT WE NEED TO DO THE JOB RIGHT.

I THINK I POSSESS A CERTAIN AMOUNT OF CREDIBILITY, BOTH WITH YOU AND THE GENERAL PUBLIC. I HOPE MY REMARKS TO YOU TODAY DID NOT COST ME SOME OF MY CREDIBILITY WITH SOME OF YOU BECAUSE YOU DON'T LIKE WHAT I SAID. I THINK YOU ALL KNOW THAT MEDICINE IN AMERICA IS IN DEEP TROUBLE, MAYBE AT A TRUE CROSSROADS.

IF YOU DON'T WANT TO SEE US TAKE THE ROAD TO CANADA, OR GREAT BRITAIN, SO SOMETHING NOW. WE MUST DO SOMETHING, SOMETHING TO REKINDLE THE LOVE OF OUR PROFESSION, THE PRIDE IN LOFTY ETHICS, THE ENJOYMENT OF MEDICINE.

DON'T JUST WRING YOUR HANDS AND GRUMBLE BECAUSE "THEY" HAVEN'T DONE SOMETHING.

YOU ARE THEY.

<https://profiles.nlm.nih.gov/spotlight/qq/feature/biographical-overview>

..... Through his speeches, publications, and films Koop rose to prominence among anti-abortion activists, and eventually came to the attention of newly-elected president and abortion foe Ronald Reagan, who nominated Koop as U.S. Surgeon General in March 1981. During eight months of controversy and congressional hearings, critics and supporters debated his stance on abortion as well as the question whether Koop, who had devoted his career to treating individual patients, was qualified to address the health needs of the nation as a whole. He was confirmed as U.S. Surgeon General in November 1981.

During his two terms as Surgeon General, Koop made himself the most prominent government spokesman on issues affecting the health of the American public, despite having little statutory authority and a small budget. He infused a renewed sense of confidence and purpose into the Commissioned Corps of the U.S. Public Health Service (PHS), a federal service of public health professionals that the Surgeon General commands and that had been suffering from low morale after the closing of PHS hospitals and the cut-back in personnel in the early 1980s. He examined medical ethics,

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**Prevention:** *Active Immunization:* Vaccines

health care costs, and the problem of the uninsured in a health care system that faced financial challenges at a time of inflation followed by recession in the early 1980s. ...

- 209) 2013-04 Klitzman R: How IRBs view and make decisions about coercion and undue influence. J Med Ethics 2013 April; 39(4): 224-229.  
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3604028/pdf/nihms433356.pdf>
- 210) 2013-04-30 Rabin RC: Health Care's 'Dirty little secret': No one may be coordinating care. KHN story was produced in collaboration with The Washington Post.  
<https://khn.org/news/coordination-of-care/>
- 211) 2013-06-26 HealthCare.gov: Patient protection and Affordable Care Act.  
<https://www.healthcare.gov/glossary/patient-protection-and-affordable-care-act/>
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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*  
**Prevention:** *Active Immunization:* Vaccines



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- 227) 2015-08-22 Pellegrini C: Robert Condon MD FACS 1929-2015: In Memory. World J Surg 2015; 39: 2611-2612. <https://www.readcube.com/articles/10.1007%2Fs00268-015-3226-y>

- 228) 2015-09-17 HHS.gov, U.S. Department of Health and Human Services: What is the cost for getting records under the FOIA? <https://www.hhs.gov/foia/faqs/what-is-the-cost-for-getting-records-under-the-foia/index.html>

While the website above the generalities, to submit FOIA request is somewhat complicated and the following disclaimer for the NIH—National Institutes of Health in part is: ...Please submit all requests through our online portal (link below) rather than mail, fax, or courier, to ensure timely logging of your requests....

First (1): <https://www.nih.gov/institutes-nih/nih-office-director/office-communications-public-liaison/freedom-information-act-office/submitting-foia-requests>

Next (2): click on the Submit a FOIA Request:

Submit a FOIA Request

Next (3): The following disclaimer will show up which after reading it, if one wishes to proceed, you should click on “I Accept”:

You are about to access a United States Government computer system. This information system is provided for U.S. Government-authorized use only. Unauthorized or improper use of this system may result in disciplinary action, as well as civil and criminal penalties.

By using this information system, you understand and consent to the following:

- You have no reasonable expectation of privacy regarding any communication or data transiting or stored on this information system. At any time, and for any lawful Government purpose, the government may monitor, intercept, and search and seize any communication or data transiting or stored on this information system.
- Any communication or data transiting or stored on this information system may be disclosed or used for any lawful Government purpose.

No particular form is prescribed for making a FOIA request. You may submit a FOIA request using the NIH FOIA Request Portal or in any manner that conforms to the HHS FOIA regulations. <http://www.hhs.gov/foia/statutes-and-resources/45cfr5/index.html>

### Privacy Act Statement

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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*  
**Prevention:** *Active Immunization:* Vaccines

This Statement is provided pursuant to the Privacy Act of 1974 (5 U.S.C. § 552a): The information you are requested to provide in order to use the NIH FOIA Request Portal is authorized to be collected under the Freedom of Information Act (5 U.S.C. § 552). Completing the request portal fields is voluntary, but failing to provide any or all of the requested information may prevent HHS from creating a portal account for you, or may prevent HHS from processing your request. The principal purposes for which HHS will use the information that you provide in the NIH FOIA Request Portal are to create an account for you, and to track, process, and respond to requests that you submit to HHS through your account. The information you provide will be included in a Privacy Act system of records, and will be used and may be disclosed for the purposes and routine uses described and published in the following System of Records Notice (SORN): 09-90-0058 Tracking Records and Case Files for FOIA and Privacy Act Requests and Appeals <https://www.federalregister.gov/articles/2016/03/29/2016-07060/privacy-act-of-1974-system-of-records-notice>  
<https://www.congress.gov/114/bills/s337/BILLS-114s337enr.xml>  
<https://www.justice.gov/oip/freedom-information-act-5-usc-552>

All requests received after 5 pm Eastern Time, will be considered "received" on the next business day.

Next (4): You will then be electronically directed to: The NIH Website for submissions.

Next (5) When you actually submit the prose of your request, you should request:

NIAID Case #12276  
NIH National Institute of Allergy and Infectious Diseases

Which was opened on June 10, 2020 in which the correspondence stated:  
“...Due to his professional responsibilities, Dr. **Fauci** has asked me to respond on his behalf.”

By:  
Kara M. Harris, MPH  
Section Chief for Controlled Correspondence and Public inquires  
Legislative Affairs and Correspondence Management Branch  
Office of Communications and Governmental Relations  
National Institute of Allergy and Infectious Diseases  
National Institutes of Health

After reviewing Dr. **Fauci**'s *White House* slide show on Monoclonal Antibodies of August 24, 2021, 10:30 to 15:27 minutes on the URL, I called Ms. Harris's office on 8/30/2021 leaving a message requesting that Dr. **Fauci** call me. In a phone response to my phone call (my VA office phone number is: 314-652-

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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*  
**Prevention:** *Active Immunization:* Vaccines

4100 ext 54463), “Meg” who identified herself from Ms. Harris’s office responding for their office stated that all the information I had submitted had been forwarded to the appropriate divisions. I then pleaded my case with “Meg” who patiently listened for about twenty minutes. Finally, when she stated she needed to go, she stated in her parting comments that she assured me that they still had all the information I had submitted in NIAID Case #12276. **Thus, under FOIA, all in NIAID Case #12276 should be available to anyone properly requesting it under Federal Law.**

[Please note Dr. **Fauci**’s opening comments in his *White House* slide show:

<https://www.youtube.com/watch?v=AZNP05w2cxU>

DR. **FAUCI**: Thank you very much, Dr. Walensky. I’d like to spend the next couple of minutes in addressing a **much-underutilized intervention for COVID-19, and that is the use of monoclonal antibodies for the TREATMENT and PREVENTION of SARS-CoV-2 infection and COVID-19 disease.**

Next slide.

For those not totally familiar with this, monoclonal antibody is an antibody that’s produced by a single clone of B cells or a cell line, and consists of identical antibody molecules that can actually be produced in the in-vitro situation in unlimited quantities.

Next slide.

If you look at the virion on the upper-left part of the slide and you look up the blown-up spike protein — the red molecule on the right upper panel — **when you talk about polyclonal antibodies, which result from infection or vaccination, it’s a group of antibodies against every aspect of the spike protein, which is the good news. However, the concentration and the affinity of those antibodies can be markedly improved if you get a single cloned antibody — hence the word “monoclonal” — that’s against the very specific part of the spike protein that can have a major effect in prevention and treatment. ...]**

**229)** 2015-12 In Memoriam—Robert Condon, MD. University of Washington Medicine, Surgery Synopsis 2015 Winter; 20 (1): 13.  
[http://uwsurgery.org/images/site/synopsis/vol20issue1/SurgSynopsis\\_Wtr2015\\_FINAL.pdf](http://uwsurgery.org/images/site/synopsis/vol20issue1/SurgSynopsis_Wtr2015_FINAL.pdf)

**230)** 2015-12 Metcalf CJE, Ferrari M, Graham AL, Greenfell BT: Understanding herd immunity. Trends Immunol 2015 Dec; 36(12): 753-755.  
<https://kilpatrick.eeb.ucsc.edu/wp-content/uploads/2013/04/Metcalf-et-al-2015-Trends-Immuno.pdf>

**231)** 2015-12-15 Sorensen CG, Karlsson WK, Pommergaard HC, Burcharth J, Rosenberg J: The diagnostic accuracy of carcinoembryonic antigen to detect colorectal cancer recurrence –

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**Treatment:** Passive Immunization: COVID-19 Convalescent Plasma and Antibodies and Antivirals  
**Prevention:** Active Immunization: Vaccines

A systematic review. *International J Surg* 2016; 25: 134-144.

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- 232)** 2016 Marano G, Vaglio S, Pupella S, Gacco G, Catalano L, Liumbruno GM, Grazzini G: Convalescent plasma: new evidence for an old therapeutic tool?  
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4781783/pdf/blt-16-152.pdf>

- 233)** 2016-02-25 Shander A, Ozawa S, Hofmann: Activity-based costs of plasma transfusions in medical and surgical inpatients at a US hospital. *VoxSanguinis*.  
<https://onlinelibrary.wiley.com/doi/full/10.1111/vox.12386>

- 234)** 2016-03-24 Freischlag JA: Bouncing Up: Resilience and women in academic medicine. Olga M Jonasson lecture. *J America College of Surgeons*  
<https://www.readcube.com/articles/10.1007%2Fs00268-015-3226-y>

- 235)** 2016-04-03 Ball P: The truth about Hannibal's route across the Alps. *The Guardian*  
<https://www.theguardian.com/science/2016/apr/03/where-muck-hannibals-elephants-alps-italy-bill-mahaney-york-university-toronto>

- 236)** 2016-05-01 Graham BS, Ambrosino DM: History of passive antibody administration for prevention and treatment of infectious diseases. *Curr Opin HIV AIDS* 2015 May; 10(3): 129-134. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4437582/>

- 237)** 2016-06-02 NEJM Knowledge+ Team: Exploring the ACGME Core Competencies (Part 1 of 7). <https://knowledgeplus.nejm.org/blog/exploring-acgme-core-competencies/>

Exploring the ACGME Core Competencies: (Part 1 of 7)

<https://knowledgeplus.nejm.org/blog/exploring-acgme-core-competencies/>

Exploring the ACGME Core Competencies: Practice-based learning and improvement (Part 2 of 7) <https://knowledgeplus.nejm.org/blog/practice-based-learning-and-improvement/>

Exploring the ACGME Core Competencies: Patient Care and Procedural Skills (Part 3 of 7) <https://knowledgeplus.nejm.org/blog/patient-care-procedural-skills/>

Exploring the ACGME Core Competencies: Systems-Based Practice (Part 4 of 7) <https://knowledgeplus.nejm.org/blog/acgme-core-competencies-systems-based-practice/>

Exploring the ACGME Core Competencies: Medical Knowledge (Part 5 of 7) <https://knowledgeplus.nejm.org/blog/acgme-core-competencies-medical-knowledge/>

Exploring the ACGME Core Competencies: Interpersonal and Communication Skills (Part 6 of 7) <https://knowledgeplus.nejm.org/blog/acgme-core-competencies-interpersonal-and-communication-skills/>

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Exploring the ACGME Core Competencies: Professionalism (Part 7 of 7)  
<https://knowledgeplus.nejm.org/blog/acgme-core-competencies-professionalism/>

- 238) 2016-07 Gupta KK, Attri JP, Singh A, Kaur H, Kaur G: Basic concepts for sample size calculation: Critical Step for any clinical trials! Saudi J Anaesth 2016 Jul-Sep; 10 (3): 328-331. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4916819/pdf/SJA-10-328.pdf>
- 239) 2016-08-09 Behrns KE: *Curriculum vitae* of Kevin E. Behrns, M.D., F.A.C.S., co-editor-in-chief of *Surgery*. <https://com-surgery-main.sites.medinfo.ufl.edu/files/2016/08/View-Kevin-Behrns-curriculum-vitae.pdf>

In July 2020, Dr. Behrns was a General Surgeon of the Department of Surgery, Saint Louis University School of Medicine; co-Editor-in-Chief of *Surgery*; and was a fellow faculty member in General Surgery Division, Department of Surgery, Saint Louis University School of Medicine of Saint Louis University and shared the General Surgery outpatient offices with me on Friday mornings. Knowing that he had graduated from the Mayo Clinic Medical School and had been a Surgery resident and researcher at the Mayo Clinic in the 1990's, I requested of him that he contact Michael Joyner, M.D., the Principal Investigator for the Mayo Clinic / FDA Expanded Access program for COVID-19 Convalescent Plasma. Dr. Joyner responded with a brief e-mail response to Dr. Behrns:

### Having a lot of trouble with USG.

By that time in July 2020, I had submitted to the offices of Dr. Fauci, Dr. Hahn, and President Trump multiple communications regarding *Passive Immunization treatment* with COVID-19 Convalescent Plasma which had been included in my submissions 1.) to the U.S. Copyright Office to be preserved for history in the Library of Congress and 2.) had been included in NIH NIAID case #12276:

1. Andrus CH: **Time:** The Crucial *Independent* Variable of the COVID-19 Pandemic, U.S. Copyright Office, Library of Congress, 2020-06-08, Txu002199029. [https://web.archive.org/web/20210904014401/https://cocatalog.loc.gov/cgi-bin/Pwebrecon.cgi?v1=9&ti=1%2C9&Search\\_Arg=Andrus+Charles+H&Search\\_Code=NALL&CNT=25&PID=DvTGOW\\_Qvd\\_foYxTfrVcdewL3ktMCwz&SEQ=20210425193720&SID=1](https://web.archive.org/web/20210904014401/https://cocatalog.loc.gov/cgi-bin/Pwebrecon.cgi?v1=9&ti=1%2C9&Search_Arg=Andrus+Charles+H&Search_Code=NALL&CNT=25&PID=DvTGOW_Qvd_foYxTfrVcdewL3ktMCwz&SEQ=20210425193720&SID=1)
2. Andrus CH: The Mayo Clinic "Safety Update" should be classified as a completed Phase I trial of COVID-19 convalescent plasma. U.S. Copyright Office, 2020-07-22, TXu002214049. [https://web.archive.org/web/20210904020833/https://cocatalog.loc.gov/cgi-bin/Pwebrecon.cgi?v1=6&ti=1%2C6&Search\\_Arg=andrus+charles+h&Search](https://web.archive.org/web/20210904020833/https://cocatalog.loc.gov/cgi-bin/Pwebrecon.cgi?v1=6&ti=1%2C6&Search_Arg=andrus+charles+h&Search)

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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*  
**Prevention:** *Active Immunization:* Vaccines

[h Code=NALL&CNT=25&PID=cXfFuGrmHQvLVILvfNNt7Yjwh73ImgQ  
&SEQ=20210512081428&SID=1](https://www.fda.gov/oc/foia/Code=NALL&CNT=25&PID=cXfFuGrmHQvLVILvfNNt7Yjwh73ImgQ&SEQ=20210512081428&SID=1)

**Dear Mr. President,** please note that all information I have submitted over the last two years to Dr. Fauci was directed by Dr. Fauci to be dealt with by:

Kara M. Harris, MPH  
Section Chief for Controlled Correspondence and Public Inquiries  
Legislative Affairs and Correspondence Management Branch  
Office of Communications and Governmental Relations  
National Institute of Allergy and Infectious Diseases  
National Institutes of Health

Per her letter of June 10, 2020, Ms. Harris assigned my correspondence with Dr. Fauci's office to NIAID Case #12276 and I have continued to submit my correspondence addressed with Dr. Fauci's office for the last two years labelled in the heading: NIAID Case#12276. After reviewing Dr. **Fauci**'s *White House* slide show on Monoclonal Antibodies of August 24, 2021, 10:30 to 15:27 minutes on the URL, *I called Ms. Harris's office on 8/30/2021 leaving a message requesting that Dr. **Fauci** call me. In a phone response to my phone call (my VA office phone number is: 314-652-4100 ext 54463), "Meg" who identified herself from Ms. Harris's office responding for their office stated that all the information I had submitted had been forwarded to the appropriate divisions. I then pleaded my case with "Meg" who patiently listened for about twenty minutes. Finally, when she stated she needed to go, she stated in her parting comments that she assured me that they still had all the information I had submitted in NIAID Case #12276. Thus, under the Freedom of Information Act (FOIA), all in NIAID Case #12276 should be available to anyone properly requesting it under Federal Law.*

**Mr. President,** please excuse my digressing from Dr. Joyner's e-mail response to Dr. Behrns of: **Having a lot of trouble with USG.** **Mr. President,** could you please excuse the 'expletives' (E!) that I will include in my discussion that follows because over the course of the last two years the American people (and the World) have been misled, misinformed, and lied to (E!) regarding major issues of treatment of COVID=19 by agencies of the Federal Government (e.g., FDA, NIH, CDC, PHS, VA, etc.), spokespersons of Organized / Academic Medicine (e.g.: *The New England Journal of Medicine*), and the Biological and Pharmaceutical industries assisted by B.A.R.D.A., other research agencies like DARPA, etc.

After Dr. Behrns voiced **Dr. Joyner's e-mail response of "having a lot of trouble with USG"**, Dr. Behrns questioned me as to who was **USG?** My response was simple: **USG is the United States Government;** and Dr. Joyner was referring off-handedly to a nebulous but responsible/accountable **USG.** I then explained that the **USG** had so *screwed up* (E!) that "they" didn't know how to get out of the rabbit hole.

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- 240) 2016-09-27 U.S. Federal Register: Clinical Trials Registration and Results Information Submission. A Rule by the Health and Human Services Department on 09/21/2016. Phase I meaning in 21 CFR 312.21. <https://www.federalregister.gov/documents/2016/09/21/2016-22129/clinical-trials-registration-and-results-information-submission> USC 312.21 <https://www.ecfr.gov/current/title-21/chapter-I/subchapter-D/part-312/subpart-B/section-312.21>
- 241) 2016-10-11 Blavin F: Association between the 2014 Medicaid expansion and US hospital finances. JAMA 2016 Oct 11; 316 (14): 1475 -1483. <https://jamanetwork.com/journals/jama/fullarticle/2565750>
- 242) 2016-12-22 Veterans Health Administration, Research & Development: Milestones in VA-Academic Collaboration. [https://www.research.va.gov/researchweek/press/\\_packet/Collaboration.pdf](https://www.research.va.gov/researchweek/press/_packet/Collaboration.pdf)
- 243) 2017 American College of Surgeons: The evolution of the Fellowship Pledge. <https://www.facs.org/about-acs/archives/pasthighlights/pledge>
- 244) 2017-01-12 Keown A: Trump says pharma getting away with murder, vows to lower drug prices. Biospace.com <https://www.biospace.com/article/-b-trump-b-says-pharma-getting-away-with-murder-vows-to-lower-drug-prices/>
- 245) 2017-01-28 U.S. National Institutes of Health, U.S. Department of Health and Human Services: NIH policy on the dissemination of NIH-funded clinical trial information. Notice Number: NOT-OD-16-149, Release Date: September 16, 2016, Effective Date: January 18, 2017. <https://grants.nih.gov/grants/guide/notice-files/not-od-16-149.html>
- 246) 2017-01-31 Georgetown Preparatory School: The Honorable Neil Gorsuch '85 nominated to serve on the U.S. Supreme Court. <https://www.gprep.org/about/news/~post/the-honorable-neil-gorsuch-85-nominated-to-serve-on-the-us-supreme-court-20170131>
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- 248) 2017-02-03 McGough M: Opinion: Neil Gorsuch was a teenage wisenheimer, not a teenage fascist. LA Times <https://www.latimes.com/opinion/opinion-la/la-ol-gorsuch-fascist-20170203-story.html>

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[https://www.pfizer.com/people/leadership/board\\_of\\_directors/scott\\_gottlieb-md](https://www.pfizer.com/people/leadership/board_of_directors/scott_gottlieb-md)
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1941

- The Red Cross begins National Blood Donor Service to collect blood for the U.S. military with Dr. Charles R. Drew, formerly of the Plasma for Britain program, as medical director.
- Soldiers injured during the Pearl Harbor attack are treated with albumin for shock

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[https://www.americanjournalofsurgery.com/article/S0002-9610\(16\)30526-8/fulltext](https://www.americanjournalofsurgery.com/article/S0002-9610(16)30526-8/fulltext)

**258)** 2018 Slifka MK, Amanna IJ: Passive immunization. *Plotkin's Vaccines* 2018: 84-95.

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**259)** 2018-01-04 FDA What are the different types of clinical research?

<https://www.fda.gov/patients/clinical-trials-what-patients-need-know/what-are-different-types-clinical-research>

NIH, National Institutes of Health: Glossary of Common Terms.

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**260)** 2018-01-29 STS Press Release: Keith S. Naunheim elected President of The Society of Thoracic Surgeons – Saint Louis University surgeon will focus on health care delivery and reimbursement.

[https://www.sts.org/sites/default/files/press-releases/President%20release\\_Naunheim\\_FINAL\\_FMT.pdf](https://www.sts.org/sites/default/files/press-releases/President%20release_Naunheim_FINAL_FMT.pdf)

Over the years, in Dr. Naunheim's discussions of many articles in the literature, he has pointed out to the Saint Louis University students, residents, and faculty the always-possible inherent potential skewing of a statistical analysis by excluding a large number of individuals (e.g.: infected, cancer positive, non-control individuals, etc.) from a prospective Randomized Controlled Trials (RCT) until the decreasing denominator renders the RCT underpowered and useless. He has often referred to this as: "*The Amazing Shrinking Denominator.*" The reference that follows entitled: Koehsen W: Lessons on how to lie with statistics – Timeless data literacy advice. <https://towardsdatascience.com/lessons-from-how-to-lie-with-statistics->



[57060c0d2f19](#) is analogous to Dr. Naunheim's expression of "*The Amazing Shrinking Denominator*":

Scientists are usually limited to small samples by legitimate problems, but advertisers use small numbers of participants in their favor by conducting many tiny studies, one of which will produce a positive result. Humans are not great at adjusting for sample sizes when evaluating a study which in practice means we treat the results of a 1000 person trial the same as a 10 person trial. **This is known as "insensitivity to sample size" or "sample size neglect".**

**261)** 2018-02-22 Neighbor J: RhoGAM at 50: A Columbia drug still saving lives of newborns – RhoGAM, a drug developed in the 1960s by Columbia University physicians, prevents one of the most severe and devastating diseases affecting fetuses and newborn babies and is still in use today. Columbia University Irving Medical Center.  
<https://www.cuimc.columbia.edu/news/rhogam-50-columbia-drug-still-saving-lives-newborns>

**262)** 2018-03-01 Yan F, Thall PF, Lu KH, Gilbert MR, Yuan Y: Phase I-II clinical trial design: a state-of-the-art paradigm for dose finding.  
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**263)** 2018-03-05 FDA: Vaccinia Immune Globulin Intravenous.  
<https://www.fda.gov/vaccines-blood-biologics/approved-blood-products/vaccinia-immune-globulin-intravenous-human>

VIGI (Human) Package insert: <https://www.fda.gov/media/77004/download>

VIGIV (Human) Package insert: <https://www.fda.gov/media/78174/download>

**264)** 2018-03-09 De Geest BG: Engineering the immune system with particles, step-by-step. Molecular Immunology 2018; 98: 25-27.  
<https://www.sciencedirect.com/science/article/abs/pii/S0161589018300452?via%3Dihub>

**265)** 2018-03-20 McKinley JC: President Trump must face accusations of 'Apprentice' contestant. The New York Times. <https://www.nytimes.com/2018/03/20/nyregion/trump-defamation-lawsuit-new-york-summer-zervos.html>

**266)** 2018-04-03 Mintz S: Do the Ends Justify the Means? Ethics Sage.  
<https://www.ethicsage.com/2018/04/do-the-ends-justify-the-means.html>

**267)** 2018-04-04 Zhu Z, Zhang Z, Chen W, Cai Z, Ge X, Zhu H, Jiang T, Tan W, Peng Y: Predicting the receptor-binding domain usage of the coronavirus based on kmer frequency on spike protein. Infection, genetics and evolution 2018; 61: 183-184.  
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7129160/pdf/main.pdf>

----- September 18, 2023 -----  
This is a COVID-19 Timeline Bibliography for Educational Purposes ONLY in the presentation of this information before the people of the United States of America (U.S.A.), the World, and specifically the President of the U.S.A. without any compensation to the author. All submissions including this timeline bibliography can be obtained under the Freedom of Information Act (FOIA) by formally requesting a copy of NIAID Case #12276 from the FIOA Officer of the National Institute of Allergy and Infectious Diseases (NIAID), U.S. National Institutes of Health, Bethesda, Maryland

- 268) 2018-04-19 Marston HD, Paules C, **Fauci AS**: Monoclonal antibodies for emerging infectious diseases – Borrowing from history. N Engl J Med 2018 Apr 19; 378 (16): 1469 – 1472. [https://www.nejm.org/doi/10.1056/NEJMp1802256?url\\_ver=Z39.88-2003&rft\\_id=ori:rid:crossref.org&rft\\_dat=cr:pub%20%20pubmed](https://www.nejm.org/doi/10.1056/NEJMp1802256?url_ver=Z39.88-2003&rft_id=ori:rid:crossref.org&rft_dat=cr:pub%20%20pubmed)

In the NEJM Managing Editor's interview of Dr. **Fauci** regarding this publication, Dr. **Fauci** laid out the exact same discussion and advocacy for early treatment of novel viruses with monoclonal antibodies *8 months before* SARS-CoV-2 was even seen or identified on this earth!: Morrissey S, **Fauci** A: Interview with Dr. Anthony Fauci on the use of monoclonal antibodies in the context of emerging infectious diseases. Supplement to the N Engl J Med 2018; 378: 1469-1472. (Mr. President, **please listen** to this five minute interview after reviewing Dr. Fauci's youtube slide presentation and discussion of the August 24, 2021 White House briefing (minutes 10:30 to 15:25): <https://www.youtube.com/watch?v=AZNP05w2cxU>.

The hyperlink for the 2018 NEJM Morrissey interview of Dr. Fauci is:  
<https://www.nejm.org/action/showMediaPlayer?doi=10.1056%2FNEJMdo002465&aid=10.1056%2FNEJMp1802256&area=>

*Dr. Morrissey:*

Although there is a long history of plasma derived treatments for several pathogens, only a handful of antibody therapies have been licensed for infectious diseases. But recent advances in the development of monoclonal antibodies could have important implications for our response to infectious disease outbreaks. I'm Stephen Morrissey, Managing Editor of the New England Journal of Medicine, and I am talking with Anthony Fauci, Director of the National Institute of Allergy and Infectious diseases. Dr. Fauci has coauthored a prospective article about the promise of monoclonal antibodies for rapid intervention during infectious disease outbreaks. Dr. Fauci: What are the primary benefits of using monoclonal antibodies for prevention and treatment infectious diseases? What advantages do they have over current approaches?

**Dr. Fauci:**

Well, one of the things that got us to be very interested in that is just that potential advantage. Namely, that when you have to respond, for example, to an unexpected outbreak of an infectious disease, one of the major tools against that to control it or hopefully eliminate it is development of a safe and effective vaccine. The problem with that is that the time that it takes, even when you put it on a rapid pace, the time that it takes to get a vaccine that you show to be safe and effective often falls behind and lags dramatically behind the actual outbreak itself. Whereas if you can with our techniques that we have right now which of greatly improved over the past several years to isolate and develop monoclonal antibody specific to the agent in question--you can use it much more rapidly. Obviously there's the issue of being able to scale up, but you get a monoclonal antibody in hand soon after you're confronted with an outbreak has a major advantage over the long time-honored but nonetheless rather drawn out process of developing a vaccine.

*Dr. Morrissey:*

You write in your article that several antibody therapies have been licensed for infectious diseases. What have researchers learned from the development of those therapies and for more recent attempts to create monoclonal antibodies against—say-- Ebola or Zika?

**Dr. Fauci:**

----- September 18, 2023 -----  
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Well, for example, a classic monoclonal antibody for prophylaxis against Respiratory Syncytial Virus has been developed with considerable success. We began thinking very intensively about this just literally over the past few years when we in rapid succession had to confront both the Ebola outbreak followed by the Zika outbreak. And it became very clear that during the Ebola outbreak that there were monoclonal antibodies in the form of ZMapp that was able to actually have an impact even though we did not have the opportunity of doing a very large clinical trial. We did show that there was clearly a tendency towards a benefit of this cocktail of three mouse human chimeric antibodies against Ebola, that we felt that this particular approach if perfected both in the development and scale-up of these antibodies might have an important role in future outbreaks. So, we're thinking that this is going to be something, and including for example influenza, so there have been now a couple of monoclonal antibodies that have been made against influenza. And when you think in terms of a threat of a pandemic influenza and you would want to get an antibody that would be effective in neutralizing a brand new virus well before the time it takes to develop the vaccine, here again is something that we're going to be pursuing and are pursuing at the present time.

*Dr. Morrissey:*

So how do you envision that process of developing new antibody therapies during an outbreak?

**Dr. Fauci:**

There a couple of ways of doing that. Probably the easiest way, because the technology now is so sophisticated, is to get an individual who has been infected with whatever pathogen is the one behind the outbreak. And because of the ability now to clone the B cells from the B cell repertoire and essentially fish out—and, truly metaphorically fishing-out the right B cell clones that have the specificity that you are thinking about and wanting to develop and immediately get those to be cloned, sequenced, and then the development of a high through-put process to give you monoclonal antibodies. That's something that was unheard of years ago—literally unheard of where you can actually probe and interrogate the B cell repertoire and the B cell lineage of a person who has recovered from the infection in question; and use those B cells as the source of the monoclonal antibody in question. And that's something that could be done immediately, and from the standpoint of the process of it, to be done very rapidly. So you can envision an outbreak where you have right-away, the sentinel people you have clearly getting sick from the pathogen you have in question and as they recover you just draw some blood from them and you can pull out with the techniques we have a variety of B cell clones that have various specificities and then you can test in vitro what is the best, what has the highest affinity, what is the most specific, what are the epitopes involved, and then start using them for both diagnosis, prophylaxis, and for treatment.

*Dr. Morrissey*

You talk in your article about the current high cost of production and complexity of administration of these monoclonal antibodies. So how great a limitation is that and do you foresee a time when those issues will be less of a barrier than they are now?

**Dr. Fauci:**

Well, that's a great question, and I'd have to answer totally, honestly—that it is a barrier that is substantial right now at present. But as we've done with so many other things that we've been able, we in the field, not me personally, but we in the field have been able to develop over years—is that once you get the first step namely the specificity, the effectiveness of a particular antibody, then you work on the development of scale-up. But the idea of scaling up at a reasonable cost where these antibodies can be used widely

is a challenge. But I do believe that as we get better and better at it as we have with other technologies that have started off to be very cumbersome and very expensive, I believe over time when there is accelerated interest in this approach which I believe there will be that we will be able to overcome that barrier of the ability to produce at a high degree.

*Dr. Morrissey:*

In your article, you describe three indications for monoclonal antibodies: the treatment of infected individuals, targeted prophylaxis to protect high-risk individuals, and targeted prophylaxis to interrupt transmission in populations at average risk. So which of these strategies do you think has the most potential to halt the spread of an epidemic?

**Dr. Fauci:**

Well, clearly if you are talking about halting the spread of an epidemic, the last two that you mentioned because the first one is the treatment of an infected individual. Now obviously you can say well treatment will turn out to be prevention because if you treat a particular person they may not transmit it to another; but I think the much more efficient way of preventing the expansion of an outbreak is the targeted prophylaxis either directly at high risk individuals or even at a population level to prophylaxis and interrupt transmission in people who are at average risk and that is really what we talk about in interrupting the chain of transmission. So, if you have an influenza outbreak, you may be able to use this as prophylaxis before you get a vaccine that is available to essentially have a more population-based prevention. So, I believe the high risk individuals that are targeted for prophylaxis is going to be a very important way to interrupt certain outbreaks regardless of what the source of that outbreak is.

*Dr. Morrissey:*

Finally, what will it take to increase our interest in our investment in the use of monoclonal antibodies for infectious diseases? What, for example, is NIAID doing?

**Dr. Fauci:**

Let me answer your question broadly, then I will get back to the specific of what we are doing. Really nothing succeeds like success as they say. Once you start demonstrating the effectiveness of this approach in different outbreaks—and we have seen inklings of this with the ZMapp approach to Ebola with some of the monoclonal antibodies—all-be-it in the animal models with Zika, they worked very well in the animal models to prevent the transmission of the virus to a fetus in an animal model; and thus prevented the congenital defects in this animal model. I believe that when we get to the point of testing it in humans, under these circumstances, we will see similar success. So, that is what I mean by nothing succeeds like success once you have a few examples of successful application of this particular approach. You are going to get a lot more interest in it. What we at NIH are doing is what we do most of the time is these types of approaches; and that is, to do the basic and clinical research to get this developmental process to be quick and to be effective. We done that and it ranges all the way from the fundamental basic research on B cell lineage--that really led to the ability to develop monoclonal antibodies at a high degrees of specificity and the high degree of ability to neutralize whatever a particular pathogen you have in question. So, the NIH 's job will be what we have been doing all a long, is the fundamental basis to give clinical research leading to the application of these types of interventions.

*Dr. Morrissey:*

Thank you, Dr. Fauci.

- 269) 2018-05-08 NIH, NIAID: H. Clifford Lane, M.D., NIAID Deputy Director, Clinical Research and Special Projects, Director, Division of Clinical Research.  
<https://www.niaid.nih.gov/about/h-clifford-lane-md-bio>
- 270) 2018-05-30 President Trump signed into law PL-115-176: Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina, the RIGHT TO TRY ACT OF 2017.  
<https://www.govinfo.gov/content/pkg/PLAW-115publ176/pdf/PLAW-115publ176.pdf>

What is on the following pages is a copy of Public Law 115-176. As is stated in **SEC. 561 B. INVESTIGATIONAL DRUGS FOR USE BY ELIGIBLE PATIENTS**, (a), (2)the term ‘eligible investigational drug’ means an investigational drug (as such term is used in section 561)—(A) **for which a Phase 1 clinical trial has been completed**; (B) that has not been approved or licensed for any use under section 505 of this Act or section 351 of the Public Health Service Act; **Throughout** the COVID-19 Pandemic over the last 16 months, the FDA and the NIH in all announcements, policy statements, etc. have equated *safety* with *efficacy*—**WHICH IS A MISINTERPRETATION OF PL-115-176.** Distinctly by FDA and NIH definitions, **Phase 1 clinical trials** are **SAFETY** clinical trials while **Phase 2 and 3 clinical trials** are **EFFICACY** clinical trials. In short, when a **Phase 1 clinical trial** is deemed “Completed” by the FDA, the *Investigational* drug or biologic should be available to all individuals who have contracted a potentially terminal disease like COVID-19 under PL-115-176 until the FDA designates a New Drug Authorization number making the drug or biologic non-investigational and thus available to all. By the FDA NOT “officially” declaring “Completed” Phase 1 clinical trials for any of the **Passive Immunization agents** and by RADM Denise Hinton, R.N., M.S. issuing Emergency Use Authorizations (EUA) for all **Passive Immunization agents**, all **Passive Immunization agents** are **ALL** *INVESTIGATIONAL* at present time.



Public Law 115–176  
115th Congress

An Act

May 30, 2018  
[S. 204]

To authorize the use of unapproved medical products by patients diagnosed with a terminal illness in accordance with State law, and for other purposes.

Trickett Wendler,  
Frank Mongiello,  
Jordan McLinn,  
and Matthew  
Bellina Right to  
Try Act of 2017.  
21 USC 301 note.

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

**SECTION 1. SHORT TITLE.**

This Act may be cited as the “Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017”.

**SEC. 2. USE OF UNAPPROVED INVESTIGATIONAL DRUGS BY PATIENTS DIAGNOSED WITH A TERMINAL ILLNESS.**

(a) IN GENERAL.—Chapter V of the Federal Food, Drug, and Cosmetic Act is amended by inserting after section 561A (21 U.S.C. 360bbb–0) the following:

21 USC  
360bbb–0a.

**“SEC. 561B. INVESTIGATIONAL DRUGS FOR USE BY ELIGIBLE PATIENTS.**

“(a) DEFINITIONS.—For purposes of this section—

“(1) the term ‘eligible patient’ means a patient—

“(A) who has been diagnosed with a life-threatening disease or condition (as defined in section 312.81 of title 21, Code of Federal Regulations (or any successor regulations));

“(B) who has exhausted approved treatment options and is unable to participate in a clinical trial involving the eligible investigational drug, as certified by a physician, who—

“(i) is in good standing with the physician’s licensing organization or board; and

“(ii) will not be compensated directly by the manufacturer for so certifying; and

“(C) who has provided to the treating physician written informed consent regarding the eligible investigational drug, or, as applicable, on whose behalf a legally authorized representative of the patient has provided such consent;

“(2) the term ‘eligible investigational drug’ means an investigational drug (as such term is used in section 561)—

“(A) for which a Phase 1 clinical trial has been completed;

“(B) that has not been approved or licensed for any use under section 505 of this Act or section 351 of the Public Health Service Act;

“(A) for which a  
Phase 1 clinical  
trial has been  
completed;

PUBLIC LAW 115–176—MAY 30, 2018

132 STAT. 1373

“(C)(i) for which an application has been filed under section 505(b) of this Act or section 351(a) of the Public Health Service Act; or

“(ii) that is under investigation in a clinical trial that—

“(I) is intended to form the primary basis of a claim of effectiveness in support of approval or licensure under section 505 of this Act or section 351 of the Public Health Service Act; and

“(II) is the subject of an active investigational new drug application under section 505(i) of this Act or section 351(a)(3) of the Public Health Service Act, as applicable; and

“(D) the active development or production of which is ongoing and has not been discontinued by the manufacturer or placed on clinical hold under section 505(i); and

“(3) the term ‘phase 1 trial’ means a phase 1 clinical investigation of a drug as described in section 312.21 of title 21, Code of Federal Regulations (or any successor regulations).

Definition of a  
‘phase 1 trial’

“(b) EXEMPTIONS.—Eligible investigational drugs provided to eligible patients in compliance with this section are exempt from sections 502(f), 503(b)(4), 505(a), and 505(i) of this Act, section 351(a) of the Public Health Service Act, and parts 50, 56, and 312 of title 21, Code of Federal Regulations (or any successor regulations), provided that the sponsor of such eligible investigational drug or any person who manufactures, distributes, prescribes, dispenses, introduces or delivers for introduction into interstate commerce, or provides to an eligible patient an eligible investigational drug pursuant to this section is in compliance with the applicable requirements set forth in sections 312.6, 312.7, and 312.8(d)(1) of title 21, Code of Federal Regulations (or any successor regulations) that apply to investigational drugs.

“(c) USE OF CLINICAL OUTCOMES.—

“(1) IN GENERAL.—Notwithstanding any other provision of this Act, the Public Health Service Act, or any other provision of Federal law, the Secretary may not use a clinical outcome associated with the use of an eligible investigational drug pursuant to this section to delay or adversely affect the review or approval of such drug under section 505 of this Act or section 351 of the Public Health Service Act unless—

“(A) the Secretary makes a determination, in accordance with paragraph (2), that use of such clinical outcome is critical to determining the safety of the eligible investigational drug; or

Determination.

“(B) the sponsor requests use of such outcomes.

“(2) LIMITATION.—If the Secretary makes a determination under paragraph (1)(A), the Secretary shall provide written notice of such determination to the sponsor, including a public health justification for such determination, and such notice shall be made part of the administrative record. Such determination shall not be delegated below the director of the agency center that is charged with the premarket review of the eligible investigational drug.

Notice.  
Records.

“(d) REPORTING.—

“(1) IN GENERAL.—The manufacturer or sponsor of an eligible investigational drug shall submit to the Secretary an annual summary of any use of such drug under this section. The summary shall include the number of doses supplied, the

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Regulations.

number of patients treated, the uses for which the drug was made available, and any known serious adverse events. The Secretary shall specify by regulation the deadline of submission of such annual summary and may amend section 312.33 of title 21, Code of Federal Regulations (or any successor regulations) to require the submission of such annual summary in conjunction with the annual report for an applicable investigational new drug application for such drug.

“(2) POSTING OF INFORMATION.—The Secretary shall post an annual summary report of the use of this section on the internet website of the Food and Drug Administration, including the number of drugs for which clinical outcomes associated with the use of an eligible investigational drug pursuant to this section was—

“(A) used in accordance with subsection (c)(1)(A);

“(B) used in accordance with subsection (c)(1)(B); and

“(C) not used in the review of an application under section 505 of this Act or section 351 of the Public Health Service Act.”.

21 USC  
360bbb-0a note.

(b) NO LIABILITY.—

(1) ALLEGED ACTS OR OMISSIONS.—With respect to any alleged act or omission with respect to an eligible investigational drug provided to an eligible patient pursuant to section 561B of the Federal Food, Drug, and Cosmetic Act and in compliance with such section, no liability in a cause of action shall lie against—

(A) a sponsor or manufacturer; or

(B) a prescriber, dispenser, or other individual entity (other than a sponsor or manufacturer), unless the relevant conduct constitutes reckless or willful misconduct, gross negligence, or an intentional tort under any applicable State law.

(2) DETERMINATION NOT TO PROVIDE DRUG.—No liability shall lie against a sponsor manufacturer, prescriber, dispenser or other individual entity for its determination not to provide access to an eligible investigational drug under section 561B of the Federal Food, Drug, and Cosmetic Act.

(3) LIMITATION.—Except as set forth in paragraphs (1) and (2), nothing in this section shall be construed to modify or otherwise affect the right of any person to bring a private action under any State or Federal product liability, tort, consumer protection, or warranty law.

21 USC  
360bbb-0a note.

### SEC. 3. SENSE OF THE SENATE.

It is the sense of the Senate that section 561B of the Federal Food, Drug, and Cosmetic Act, as added by section 2—

(1) does not establish a new entitlement or modify an existing entitlement, or otherwise establish a positive right to any party or individual;

(2) does not establish any new mandates, directives, or additional regulations;

(3) only expands the scope of individual liberty and agency among patients, in limited circumstances;

(4) is consistent with, and will act as an alternative pathway alongside, existing expanded access policies of the Food and Drug Administration;

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132 STAT. 1375

(5) will not, and cannot, create a cure or effective therapy where none exists;

(6) recognizes that the eligible terminally ill patient population often consists of those patients with the highest risk of mortality, and use of experimental treatments under the criteria and procedure described in such section 561A involves an informed assumption of risk; and

(7) establishes national standards and rules by which investigational drugs may be provided to terminally ill patients.

Approved May 30, 2018.

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LEGISLATIVE HISTORY—S. 204:

CONGRESSIONAL RECORD:

Vol. 163 (2017): Aug. 3, considered and passed Senate.

Vol. 164 (2018): May 22, considered and passed House.

DAILY COMPILATION OF PRESIDENTIAL DOCUMENTS (2018):

May 30, Presidential remarks.

- 271) 2018-06-28 Zolkefli Y: The ethics of truth-telling in health-care setting. Malays J Med Sci 2018; 25(3): 135-139.  
[https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6422557/pdf/14mjms25032018\\_sc.pdf](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6422557/pdf/14mjms25032018_sc.pdf)
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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*  
**Prevention:** *Active Immunization:* Vaccines



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Dr. Johnson was born in Evanston, IL, on October 28, 1943 to Frank Edward Johnson, Sr. and Beryl Madeline Johnson. He received his undergraduate and medical degrees from the University of Minnesota in Minneapolis and completed his internship at the University of California Los Angeles. He then traveled around the world for one year prior to serving as a naval doctor during the Vietnam War. He was awarded the Bronze Star Medal for acts of valor and heroism. His time in Vietnam inspired him to work with his dad to create a charitable organization that continues to bring children with cardiac defects from around the world to the US for surgery.

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## The Dog Lab

## Chapter

With many exotic new methods of conducting medical experiments including genetic testing and high technology in general, there remains a tried and true method of conducting the testing of innovative and potentially life-saving operations and procedures: the “dog lab.” For the research physician, physiologist, and surgeon alike, the laboratory specializing in the use of large animals, e.g.: dogs, is the place that physicians are able to test procedures before they are attempted on human beings. Organ transplantation, the development of procedures using endoscopic instruments, the use of lasers to perform surgery on the human eye and even surgery through the use of remote controlled robots all had their beginnings in *The Dog Lab*.

Human nature is not only averse to being exposed to the grittiness of life but it collectively wretches in response to such exposures. As demonstrated by Hurricane Katrina in August of 2005, life’s realities are stark, stomach turning and piercing. And yet, much of modern life is littered with a grittiness that we cannot indulge in the focus of the mind’s eye. Whether it is the irresolvable nature and sordidness of abortion, the unimaginable, brutal and inhumane nature of the Nazi experiments on human beings or research of the Tuskegee Study of African Americans with syphilis in which penicillin was deliberately withheld in an effort to better understand how the disease is spread and what its effects are on the human body, we have little stomach for such mind numbing sordidness. The slaughtering of animals for their fur and for the protein flesh they provide for our daily fare comes even closer to scarring placid images of the good life as it is lived on a daily basis.

The use of dogs as vehicles for surgeons to learn how to perform new operations strikes a similar chord. It is abrasive to human consciousness to think that dogs are expendable for such purposes, especially since so many fellow citizens treasure them as family members. Dog labs are decades old and by nature experimental. Given their unsung role in the development of American surgical procedures, it is no small wonder that legions of dogs have

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## The Dog Lab

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been sacrificed on the altar of learning. As such, dog labs have come to represent a slaughter house of sorts, a place where the life of an animal is put at risk or sacrificed for the good of learning how to do something that would be of benefit to human kind. Due to the bloody and unsavory light in which the dog lab has come to be cast in the minds of surgical medicine, the dog lab has come to represent disparaging metaphor of sometime unconscionable practices.

Many years ago, the term “dog lab” was used as an instructional metaphor to then this newly named Veterans Administration (VA) hospital’s Chief of Surgery. A fellow senior surgeon offered the term as a description and an explanation of how some physicians have historically viewed the relationship between VA hospitals in general and the medical schools with which they affiliated over the course of the last sixty years. Thus, historically, the metaphor epitomizes the derogatory sentiments and allusions that some physicians and medical educators have made in the presence of their educational charges regarding the indigent and less-fortunate who are treated in our nation’s largest public hospital system.

The callous use of such a demeaning metaphor signals nothing less than a diminishment of human worth. In the verbal attitudes they express, all too often medical educators as role models convey implied values that impart heavy and unfortunately lasting meaning for their students. It is the method by which values both ill and good are transmitted over the course of generations. Even if untrue<sup>1</sup> initially and intended in reference to only one VA hospital, “The Dog Lab” is unimaginably derogatory to the U.S. Department of Veterans Affairs as an institution implying a substandard system of health care. Furthermore, it demeans and condemns those veterans who utilize the VA as their primary source of healthcare as somewhat less-than-human experimental subjects. And yet, it is the country’s veterans who exposed themselves in harms’ way to protect our way of life throughout our nation’s history. It is those same veterans who knowingly served their country not knowing when they were inducted and swore allegiance to the country whether they would be stateside for the duration of their military career or die in combat within six months of their induction. It is those very same veterans to whom Abraham Lincoln 140 years ago promised on our behalf: **“...to care for him who shall have borne the battle, and for his widow, and his orphan...”** It is those veterans--the short, the long and the tall, the drug addicted or alcoholic, homeless, chronically mentally ill and rife with unrelenting PTSD--to whom we owe our way of life. The manner in which they are treated in the healthcare system dedicated to them reflects on the very character of our country.

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<sup>1</sup>VA hospitals have been recognized in recent studies as providing an above average standard of healthcare quality. See *U.S. News & World Report*. July 18, 2005

### Chapter 3

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Former Chief, Psychology Service, Edward Hines, Jr. VAH  
Former Chair, Edward Hines, Jr. VAH Ethics Committee  
Professor of Psychology, Loyola University, Chicago

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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*  
**Prevention:** *Active Immunization:* Vaccines



*How to Lie With Statistics* is a 65-year-old book that can be read in an hour and will teach you more practical information you can use every day than any book on “big data” or “deep learning.” For all promised by machine learning and petabyte-scale data, the most effective techniques in data science are still small tables, graphs, or even a single number that summarize a situation and help us — or our bosses — make a decision informed by data.

Time and again, I’ve seen thousands of work hours on complex algorithms summarized in a single number. Ultimately, that’s how the biggest decisions are made: with a few pieces of data a human can process. This is why lessons from “How to Lie with Statistics” (by Darell Huff) are relevant even though each of us probably [generates more data in a single day](#) than existed in the entire world at the writing of the book. As producers of tables and graphs, we need to effectively present valid summaries. As consumers of information, we need to spot misleading/exaggerated statistics which manipulate us to take action that benefits someone else at our expense.

These skills fall under a category called [“data literacy”](#): the ability to read, understand, argue with, and make decisions from information. Compared to algorithms or big data processing, data literacy may not seem exciting, but it should form the basis for any data science education. Fortunately, these core ideas don’t change much over time and often the best books on the subject (such as [The Visual Display of Quantitative Information](#)) are decades old. The classic book discussed in this article addresses responsible consumption of data in a concise, effective, and enjoyable format. Here are my lessons learned from “How to Lie with Statistics” with commentary from my experiences.

#### 4. Small Samples Produce Shocking Statistics

Would you be surprised if I told you the highest cancer rates tend to occur in the counties with the smallest populations? Not that shocking. How about when I add that the lowest cancer rates also tend to occur in counties with the lowest number of people? [This a verified example](#) of what occurs with small sample sizes: extreme values.

Any time researchers conduct a study, they use what is called a sample: a subset of the population meant to represent the entire population. This might work fine when the sample is large enough and has the same distribution of the larger population, but often, because of limited funding or response rates, psychological, behavioral, and medical studies are conducted with small samples, leading to results that are questionable and cannot be reproduced.

Scientists are usually limited to small samples by legitimate problems, but advertisers use small numbers of participants in their favor by conducting many tiny studies, one of which will produce a positive result. Humans are not great at adjusting for sample sizes when evaluating a study which in practice means we treat the results of a 1000 person trial the same as a 10 person trial. **This is known as “insensitivity to sample size” or “sample size neglect”.**

#### 8. Look for Bias in Sample Selection

Remember when we talked about all data being gathered from samples which we hope are representative of the population? In addition to being concerned about sample size, we also need to look for any bias in the sample.

This could come from the measurement method used: a landline phone screen might favor wealthier, older participants. It could also come from the physical location: surveying only people who live in cities because it’s cheaper might bias results toward more progressive views. Sample bias is particularly prevalent in political polling where 2016 showed that sometimes samples are not representative of an entire population.

When examining a study, we need to ask who is being included in the sample and who is being excluded. For decades, psychology and sociology studies have been hurt by the WEIRD bias. Samples only included



people (often college students) from Western, Education, Industrialized, Rich, Democratic, Nations. It's hard to reasonably say a survey represents all of humanity when the participants are this limited!

We should also look for sampling bias in our sources of information. Most of us now impose information selection bias on our selves by choosing sources that we tend to agree with. This leads to dangerous situations where we don't encounter people who have different opinions and so we grow more entrenched in our views. The solution to this is simple but difficult: read different sources of news, particularly those that don't agree with you.

If you are a New York Times reader, try the Wall Street Journal for a while. For those who are feeling adventurous, you can even try talking to people who disagree with you. While this may seem intimidating, I've found that people who disagree outwardly often have more in common — the same core driving desires — motivating them to choose their respective sides. It's much easier to come to a common understanding in person but even engaging in civil discourse online is possible and productive and can help you escape a self-imposed information-selection bias.

In summary, we need to be wary both of outside sampling bias and self-created sampling bias from our choice of media sources. You would not like someone telling you to read only a single newspaper, so don't do the same to yourself. Diverse viewpoints lead to better outcomes, and incorporating different sources of information with varying opinions will give you a better overall picture of events. We can't always get to the complete truth of a matter, but we can at least see it from multiple sides. Similarly, when reading a study, make sure you recognize that the sample may not be indicative of the entire population and try to figure out which way the bias goes.

### 9. Be Wary of "Big Names" on Studies and Scrutinize Authority

Huff describes the idea of an "O.K name" as one added to a study to lend it an air of authority. Medical professionals (doctors), universities, scientific institutions, and large companies have names that lead us to automatically trust the results they produce. However, many times these "experts" did not actually produce the work but only were tangentially involved and the name has been added to sway us. Other times, such as when cigarette makers used doctors to sell their deadly products, the [authorities are directly paid to lie](#). One way to avoid being persuaded by an impressive name is to "make sure the name on the study stands behind the study and not beside it." Don't see an institutional name and immediately assume the study is infallible. I don't think we should look at the author or university until we've analyzed the statistics to avoid any unconscious bias we impose on ourselves.

Even when the results come from a confirmed "expert" that does not mean you should accept them without question. The [argument from authority](#) is a fallacy that occurs when we assume someone with greater power is more likely to be correct. This is false because past success has no bearing on whether current results are correct. As Carl Sagan put it: "Authorities must prove their contentions like everybody else." ([from The Demon-Haunted World: Science as a Candle in the Dark](#)).

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**Prevention:** *Active Immunization:* Vaccines

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- Serologic response to SARS-CoV-2
    - One study found the serologic response to a recombinant SARS-CoV-2 nucleocapsid: IgM 85.4%, IgA 92.7% (median 5d after the onset of symptoms), and IgG 77.9% (14d after onset).[\[22\]](#)
    - Another study from China using IgM and IgG SARS-CoV-2-specific antibodies found < 40% seropositive if illness less than 7d, rising to ~100% 15d or more after onset.
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## Abstract

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Cancer patients who have exhausted standard treatments often seek access to investigational drugs. Often, however, such access is unavailable, due to either the unavailability of a trial, lack of an open recruiting spot on the trial, even when the trial itself is open, or the inability of the patient to meet one or more trial eligibility criteria. In such settings patients often seek access to investigational agents outside of a trial. The federal “Right to Try” legislation was passed to create an additional avenue, different from the FDA’s Expanded Access, or “Compassionate Use” Program, through which patients might obtain access to investigational drugs. A year after this legislation was signed into law, there remains both a limited awareness of it and a substantial degree of misunderstanding on the part of those who are aware of it. The law creates an avenue to greatly facilitate off-study administration when patient, physician and the manufacturer are all in agreement regarding the off study use of an eligible investigational agent. The law does not, however, empower a patient to impose a demand on either a provider or a drug manufacturer, nor does it require any entity to provide financial coverage for the drug. Eligible drugs are those which are not approved by the FDA for any indication, have completed a phase I trial, have an ongoing pivotal trial, and have an active registration plan. We review the specific law with commentary on its implications for improved access to investigational drugs outside of clinical trials.

## Summary.

RTT creates a pathway for patients to receive an investigational drug outside of a clinical trial if, and only if, the patient is eligible, the drug is eligible, and the patient, drug manufacturer, and treating physician all agree that they wish to pursue this path. This legislation does not empower the patient to compel either a physician or a drug company to provide a drug under this Act. For the patient to be eligible, that patient must have a life- threatening disease or condition, must have exhausted standard care options, and must not have access to the drug on a clinical trial. For the drug to be eligible, it must not be approved by the FDA for any indication, must have completed a phase I trial, and must have an ongoing pivotal trial. The number of times in which all eligibility criteria for the patient and the drug are met, and all parties agree to proceed, will be limited, however, in such scenarios, RTT provides a pathway which is far simpler and requires far less consultation, documentation, and reporting than the FDA’s Expanded Access Program, thus facilitating access to eligible investigational agents for eligible patients.

## Table 1.

### Summary of “Right to Try” Act

#### Requirements for Patient

- a. Life-threatening condition
- b. Exhausted standard treatment options
- c. Unable to participate in an ongoing trial
- d. Provide informed consent

#### Requirements for Drug

- a. Phase I trial completed
- b. Ongoing pivotal phase II or III trial
- c. Active development plan to seek FDA approval
- d. Not approved for any indication

#### Requirement for the Physician

- a. Be in good standing with licensing organization or board
- b. Certify that patient is unable to participate in a clinical trial involving the drug in question
- c. Accept written informed consent from patient or authorized representative.
- d. Receive no compensation from the Sponsor/manufacturer

#### Requirements for Sponsor/Manufacturer

- a. Comply with standard procedures for investigational drug labeling, promotion,

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and recovery of direct costs.

b. Submit an annual summary of the use of the drug to the FDA, including number of doses supplied, number of patients treated, the uses for which the drug was made available, and any known serious adverse events.

Liabilities and Mandates

- a. No liability for a manufacturer's decision not to provide drug
- b. No liability for a physician's decision not to prescribe drug
- c. No mandate for any entity to provide coverage for drug or associated care
- d. No positive right established to any individual

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<https://www.fda.gov/media/145610/download>

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes coronavirus disease 2019 (COVID-19).<sup>1</sup> On the basis of such determination, the Secretary of HHS on March 27, 2020, declared that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3), subject to terms of any authorization issued under that section.<sup>2</sup>

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**H**uman coronaviruses (HCoVs) have long been considered inconsequential pathogens, causing the “common cold” in otherwise healthy people. However, in the 21st century, 2 highly pathogenic HCoVs—severe acute respiratory syndrome coronavirus (SARS-CoV) and Middle East respiratory syndrome coronavirus (MERS-CoV)—emerged from animal reservoirs to cause global epidemics with alarming morbidity and mortality. In December 2019, yet another pathogenic HCoV, 2019 novel coronavirus (2019-nCoV), was recognized in Wuhan, China, and has caused serious illness and death. The ultimate scope and effect of this outbreak is unclear at present as the situation is rapidly evolving.

Coronaviruses are large, enveloped, positive-strand RNA viruses that can be divided into 4 genera: alpha, beta, delta, and gamma, of which alpha and beta CoVs are known to infect humans.<sup>1</sup> Four HCoVs (HCoV 229E, NL63, OC43, and HKU1) are endemic globally and account for 10% to 30% of upper respiratory tract infections in adults. Coronaviruses are ecologically diverse with the greatest variety seen in bats, suggesting that they are the reservoirs for many of these viruses.<sup>2</sup> Peridomestic mammals may serve as intermediate hosts, facilitating recombination and mutation events with expansion of genetic diversity. The surface spike (S) glycoprotein is critical for binding of host cell receptors and is believed to represent a key determinant of host range restriction.<sup>1</sup>

Until recently, HCoVs received relatively little attention due to their mild phenotypes in humans. This changed in 2002, when cases of severe atypical pneumonia were described in Guangdong Province, China, causing worldwide concern as disease spread via international travel to more than 2 dozen countries.<sup>2</sup> The new disease became known as severe acute respiratory syndrome (SARS), and a beta-HCoV, named SARS-CoV, was identified as the causative agent. Because early cases shared a history of human-animal contact at live game markets, zoonotic transmission of the virus was strongly suspected.<sup>3</sup> Palm civets and raccoon dogs were initially thought to be the animal reservoir(s); however, as more viral sequence data became available, consensus emerged that bats were the natural hosts.

Common symptoms of SARS included fever, cough, dyspnea, and occasionally watery diarrhea.<sup>2</sup> Of infected patients, 20% to 30% required mechanical ventilation and 10% died, with higher fatality rates in older patients and those with medical comorbidities. Human-to-human transmission was documented,

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mostly in health care settings. This nosocomial spread may be explained by basic virology: the predominant human receptor for the SARS S glycoprotein, human angiotensin-converting enzyme 2 (ACE2), is found primarily in the lower respiratory tract, rather than in the upper airway. Receptor distribution may account for both the dearth of upper respiratory tract symptoms and the finding that peak viral shedding occurred late ( $\approx 10$  days) in illness when individuals were already hospitalized. SARS care often necessitated aerosol-generating procedures such as intubation, which also may have contributed to the prominent nosocomial spread.

Several important transmission events did occur in the community, such as the well-characterized mini-outbreak in the Hotel Metropole in Hong Kong from where infected patrons traveled and spread SARS internationally. Another outbreak occurred at the Amoy Gardens housing complex where more than 300 residents were infected, providing evidence that airborne transmission of SARS-CoV can sometimes occur.<sup>4</sup> Nearly 20 years later, the factors associated with transmission of SARS-CoV, ranging from self-limited animal-to-human transmission to human superspreader events, remain poorly understood.

Ultimately, classic public health measures brought the SARS pandemic to an end, but not before 8098 individuals were infected and 774 died.<sup>2</sup> The pandemic cost the global economy an estimated \$30 billion to \$100 billion.<sup>1</sup> SARS-CoV demonstrated that animal CoVs could jump the species barrier, thereby expanding perception of pandemic threats.

In 2012, another highly pathogenic beta-CoV made the species jump when Middle East respiratory syndrome (MERS) was recognized and MERS-CoV was identified in the sputum of a Saudi man who died from respiratory failure.<sup>3</sup> Unlike SARS-CoV, which rapidly spread across the globe and was contained and eliminated in relatively short order, MERS has smoldered, characterized by sporadic zoonotic transmission and limited chains of human spread. MERS-CoV has not yet sustained community spread; instead, it has caused explosive nosocomial transmission events, in some cases linked to a single superspreader, which are devastating for health care systems. According to the World Health Organization (WHO), as of November 2019, MERS-CoV has caused a total of 2494 cases and 858 deaths, the majority in Saudi Arabia. The natural reservoir of MERS-CoV is presumed to be bats, yet human transmission events have primarily been attributed to an intermediate host, the dromedary camel.

MERS shares many clinical features with SARS such as severe atypical pneumonia, yet key differences are evident. Patients with MERS have prominent gastrointestinal symptoms and often acute kidney failure, likely explained by the binding of the MERS-CoV S glycoprotein to dipeptidyl peptidase 4 (DPP4), which is present in the lower airway as well as the gastrointestinal tract and kidney.<sup>3</sup> MERS necessitates mechanical ventilation in 50% to 89% of patients and has a case fatality rate of 36%.<sup>2</sup>

While MERS has not caused the international panic seen with SARS, the emergence of this second, highly pathogenic zoonotic HCoV illustrates the threat posed by this viral family. In 2017, the WHO placed SARS-CoV and MERS-CoV on its Priority Pathogen list, hoping to galvanize research and the development of countermeasures against CoVs.

The action of the WHO proved prescient. On December 31, 2019, Chinese authorities reported a cluster of pneumonia cases in Wuhan, China, most of which included patients who reported exposure to a large seafood market selling many species of live animals. Emergence of another pathogenic zoonotic HCoV was suspected, and by January 10, 2020, researchers from the Shanghai Public Health Clinical Center & School of Public Health and their collaborators released a full genomic sequence of 2019-nCoV to public databases, exemplifying prompt data sharing in outbreak response. Preliminary analyses indicate that 2019-nCoV has some amino acid homology to SARS-CoV and may be able to use ACE2 as a receptor. This has important implications for predicting pandemic potential moving forward. The situation with 2019-nCoV is

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evolving rapidly, with the case count currently growing into the hundreds. Human-to-human transmission of 2019-nCoV occurs, as evidenced by the infection of 15 health care practitioners in a Wuhan hospital. The extent, if any, to which such transmission might lead to a sustained epidemic remains an open and critical question. So far, it appears that the fatality rate of 2019-nCoV is lower than that of SARS-CoV and MERS-CoV; however, the ultimate scope and effects of the outbreak remain to be seen.

Drawing on experience from prior zoonotic CoV outbreaks, public health authorities have initiated preparedness and response activities. Wuhan leaders closed and disinfected the first identified market. The United States and several other countries have initiated entry screening of passengers from Wuhan at major ports of entry. Health practitioners in other Chinese cities, Thailand, Japan, and South Korea promptly identified travel-related cases, isolating individuals for further care. The first travel-related case in the United States occurred on January 21 in a young Chinese man who had visited Wuhan.

Additionally, biomedical researchers are initiating countermeasure development for 2019-nCoV using SARS-CoV and MERS-CoV as prototypes. For example, platform diagnostic modalities are being rapidly adapted to include 2019-nCoV, allowing early recognition and isolation of cases. Broad-spectrum antivirals, such as remdesivir, an RNA polymerase inhibitor, as well as lopinavir/ritonavir and interferon beta have shown promise against MERS-CoV in animal models and are being assessed for activity against 2019-nCoV.<sup>5</sup> Vaccines, which have adapted approaches used for SARS-CoV or MERS-CoV, are also being pursued. For example, scientists at the National Institute of Allergy and Infectious Diseases Vaccine Research Center have used nucleic acid vaccine platform approaches.<sup>6</sup> During SARS, researchers moved from obtaining the genomic sequence of SARS-CoV to a phase 1 clinical trial of a DNA vaccine in 20 months and have since compressed that timeline to 3.25 months for other viral diseases. For 2019-nCoV, they hope to move even faster, using messenger RNA (mRNA) vaccine technology. Other researchers are similarly poised to construct viral vectors and subunit vaccines.

While the trajectory of this outbreak is impossible to predict, effective response requires prompt action from the standpoint of classic public health strategies to the timely development and implementation of effective countermeasures. The emergence of yet another outbreak of human disease caused by a pathogen from a viral family formerly thought to be relatively benign underscores the perpetual challenge of emerging infectious diseases and the importance of sustained preparedness.

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**Published Online:** January 23, 2020. doi:[10.1001/jama.2020.0757](https://doi.org/10.1001/jama.2020.0757)

**Conflict of Interest Disclosures:** None reported.

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DR. SCHLEIFER: Thanks, Mr. President, for having us. I'm Lenny Schleifer, the founder and CEO of Regeneron, a company that I built with George Yancopoulos over the last 30 years. And we are a monoclonal antibody primarily centered company. We are no strangers to collaborating with the administration. We work with Secretary Azar's group, BARDA. And we came up with a cure for Ebola, and we're very proud of that. Dr. Fauci's group was really instrumental in testing that under unbelievable conditions in the Congo. And it didn't create quite as much excitement, because, thank goodness, it didn't hit our shores.



But we can use the exact same technology, and we already have. We have 1,000 antibodies that are already sitting in dishes. We're screening them. We're selecting them. We anticipate, if all goes well, 200,000 doses per month can come out of our factory in New York, starting in August.

The unique thing about our technology —

THE PRESIDENT: That means you'd be able to use the vaccine that early?

DR. SCHLEIFER: It depends on what we see; how we work closely with the FDA, which we will do. The FDA already reached out to us, but we've got to work closely.

THE PRESIDENT: So that process would be faster than John's?

DR. SCHLEIFER: It would be. The —

SECRETARY AZAR: Can you explain why that would be?

DR. SCHLEIFER: Well, so, we make passive vac- — vaccine and therapeutic — therapeutic. Our drug will be able to protect you. Whether or not you're infected, it'll protect you from getting infected. Or if you are infected, it would treat you. And the — we have just taken processes that normally take years — literally, years — and we put them end-to-end and now do them in weeks to months, which nobody else in the industry can do.

So we're very excited to collaborate once again.

THE PRESIDENT: So this would be a combination of a vaccine and also it will — to put it in a different way — make you better, quicker.

DR. SCHLEIFER: Yeah. Well, think of it this way: If you — if you get immunized with one of these vaccines, you're going to make some antibodies to protect you. We're going to already make those antibodies and give them to you so you don't have to go through that whole process. So it'll protect you.

And, as we showed with Ebola, if you give enough of them — we — it was lifesaving, life- — truly lifesaving.

THE PRESIDENT: That's true.

DR. SCHLEIFER: And it beat out the antivirals. It really — it was the way to go. It's very predictable.

I just want to say, I hope everybody succeeds here. I mean, this is — bringing everybody together here is really critical and there's going to be success. This industry is really talented, as an industry. Sometimes we run astray, but we're going to get this done.

THE PRESIDENT: Thank you very much. Thanks, Len. Appreciate it. Please.

- 333) 2020-03-02 Einkenkel W: Watch Trump's complete lack of scientific knowledge on full display in coronavirus meeting (/stories/2020/3/2/1923639/-Watch-Trump-s-complete-lack-of-scientific-knowledge-on-full-display-in-coronavirus-meeting).  
<https://www.dailykos.com/stories/2020/3/2/1923639/-Watch-Trump-s-complete-lack-of-scientific-knowledge-on-full-display-in-coronavirus-meeting>

*Dr. Leonard Schleifer, Regeneron Pharmaceuticals CEO, explains that, no, vaccines are vaccines and drugs are drugs. Dr. Schleifer: Well, think of it this way, if you get immunized with one of these vaccines, you're going to make antibodies to protect you. We are going to give you those antibodies so you don't have to go through that process.*

- 334) 2020-03-02 Facher L: Trump's tone toward pharma shifts, as he looks to drug makers to help with coronavirus response. StatNews. <https://www.statnews.com/2020/03/02/trumps-tone-toward-pharma-shifts-coronavirus/>

WASHINGTON — President Trump had billed the meeting with pharmaceutical executives as a scolding waiting to happen. The gathering was intended to pressure the industry to bring drug prices “way down,” he said on Friday, suggesting it had only later morphed into a “convenient” opportunity to discuss the development of a coronavirus vaccine.

But seated across from 10 pharmaceutical executives in the Cabinet Room on Monday, Trump's long-simmering contempt for the drug industry melted away. Trump told executives from Gilead, Johnson & Johnson, and Pfizer that they worked for a “great company.” He affectionately referred to Leonard Schleifer, the CEO of Regeneron, as “Lenny.” At one point, Trump referred to the assembled drug executives as “geniuses.”

The meeting signified a remarkable shift in Trump's view of the pharmaceutical industry. After years of maintaining that drug companies charge “ripoff” prices, Trump appeared floored by the executives' progress reports. He alternately praised CEOs and egged them on to lay out shorter and shorter timelines for bringing a vaccine to market. Trump, throughout the meeting, appeared so blown away by the drug companies' claims that his deputies struggled to rein in his expectations.

“Like I've been telling you, Mr. President,” Tony Fauci, the director of the National Institute on Allergy and Infectious Disease, interjected at one point. “A year to a year and a half,” he said, referring to the amount of time it will likely take to deploy an effective vaccine to large populations.

Undeterred, Trump continued to ask various versions of the same question: “So what do you think in terms of timing?”

The executives largely told the president what he wanted to hear — that for both therapies and vaccines, companies could enter early testing within months, with the aim of reaching the market in time for peak season in a year's time.

“It was: Tell us how fast you can go, but let's keep safety in mind, and let's make sure we create something manufacturable,” said Dan Menichella, CEO of CureVac, who was among the executives seated before Trump. The company, headquartered in Germany and Boston, uses messenger RNA to produce protective antibodies inside patients' bodies, thereby preventing infection. CureVac expects to start testing its coronavirus vaccine in healthy volunteers by June, with further trials to come if the injection proves safe.

But even as Fauci and health secretary Alex Azar interrupted to caution the president that most therapies and vaccines were nowhere near ready, the president leaned into the executives' positive spin.

“That's very exciting,” Trump said at one point to Daniel O'Day, the CEO of the biotech giant Gilead Sciences, after he described progress on a therapy that could be used to mitigate coronavirus symptoms. “Get it done, Daniel. Don't disappoint us.”

Fueling Trump's optimism: When questioned by the president, drug company representatives often struggled to differentiate between projections for bringing drugs to late-stage trials and bringing them to market — so much so that Fauci became a de facto referee.

At one point, he responded to Stephane Bancel, the chief executive officer of Moderna, with a stern clarification: “You won’t have a vaccine — you’ll have a vaccine to go into testing.”

But he immediately pivoted to Regeneron’s Schleifer.

“But Lenny is talking about two months,” Trump replied. “I mean, I like the sound of a couple of months better.”

**335) 2020-03-03 pharmaphorum: CEOs give Trump ‘Biology 101’ lesson as coronavirus causes election nerves.** <https://pharmaphorum.com/news/ceos-give-trump-biology-101-lesson-as-coronavirus-causes-election-nerves/>

- i. The meeting turned into a kind of Biology 101 lesson for a perplexed-looking Trump from the likes of [GlaxoSmithKline](#)’s CEO Emma Walmsley, Gilead’s CEO Daniel O’Day, Johnson & Johnson’s chief scientific officer Paul Stoffels, and Regeneron’s CEO Leonard Schleifer.
- ii. Health secretary Alex Azar kicked off the meeting by asking the pharma execs to find ways to hasten development of a vaccine.
- iii. And there was a sense of tension in the room as it became apparent that it’s unlikely one will be approved and ready to use ahead of the presidential elections in November.
- iv. In a progress briefing from Schleifer, Trump praised Regeneron for its progress so far before asking whether a flu vaccine would work against COVID-19.
- v. Trump said: “You take a solid flu vaccine – you don’t think that would have an impact or much of an impact on corona?”
- vi. The answer from Schleifer was a flat “no”, with Anthony [Fauci](#) from the National Institutes for Healthcare softening the blow with “probably not”.
- vii. Trump asked [Gilead](#)’s O’Day to hurry trials of its antiviral drug [remdesivir](#) begun this week, telling the CEO to “get it done”.
- viii. He added: “Don’t disappoint us, Daniel. Do you understand? Great company. Really great.”
- ix. Trump also quizzed J&J’s Stoffels about the timeline for the development of that company’s vaccine and noted that the US pharma’s vaccine will not be ready until next season.
- x. Azar went on to lay out a time frame for development of various therapeutic options for the president, noting that antivirals will likely be ready first, ahead of monoclonal antibodies from Regeneron, followed by vaccines.
- xi. Summarising, Trump said: “I will tell you, the whole thing with therapeutics, to me, is very exciting. And, obviously, vaccines. But therapeutics is very exciting, especially when you’re so far advanced. That’s great. That’s really great. Thank you.”

**336) 2020-03-05. YouTube: Regeneron’s Leonard S. Schleifer meets with Trump at the White House, 3/2/2020.** [https://www.youtube.com/watch?v=3li6p\\_stzW8](https://www.youtube.com/watch?v=3li6p_stzW8) **AT THIS MEETING, PRESIDENT TRUMP AND ALL THE PEOPLE OF THE WORLD WERE MISLED BY OMISSION / MISREPRESENTING THE DISTINCTION BETWEEN ACTIVE IMMUNIZATION (vaccines) versus PASSIVE IMMUNIZATION (convalescent plasma, convalescent sera, monoclonal antibodies, monoclonal antibody cocktail, etc.).** The cost of production of a dose (1/2 unit of fresh frozen plasma) COVID-19 Convalescent Plasma (CCP) which was available in March 2020 is ~\$200 while a dose of

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REGEN-COV™ (Casirivimab with imdevimab) which would be several months into the future and would cost ~\$3000 a dose. A monoclonal antibody is specific for one antigen (e.g. a specific site on the spike point) and is likely to be ineffective on future variants like Omicron. Polyclonal antibodies like Convalescent Plasma will have multiple antibodies of such sites as on the spike protein and will be available as the SARS-CoV-2 mutates. (e.g. more effective on the Omicron variant).

\*\*\*\*\* Full 56:54 minute meeting in *The White House* where they went around the table introducing the key players: <https://www.c-span.org/video/?469926-1/president-trump-meeting-pharmaceutical-executives-coronavirus> with the complete transcript: <https://web.archive.org/web/20200303160403/https://www.whitehouse.gov/briefings-statements/remarks-president-trump-members-coronavirus-task-force-meeting-pharmaceutical-companies/> This linchpin White House meeting included CEOs, presidents, and Medical Directors of the major biomedical and pharmaceutical companies who could provide vaccines, monoclonal antibodies, and antivirals; the Secretary of the U.S. Department of Health and Human Services and its agencies (e.g.: FDA, NIH, CDC, etc.); and the Vice-president and the President of the United States of American. 1.) Nobody defined the foundational basics of Clinical Immunology: Active Immunization and Passive Immunization. 2.) Everything was in Generalities – NOT THE INDIVIDUAL PATIENT! 3.) The not-for-profit American Red Cross was NOT officially invited “to the table” until July 30, 2020—by that time, the U.S.A. had gone so far down the Rabbit Hole, they did not know how to get out! 4.) No physician in that room, on that day, has probably cared for the individual patient since Medical School.

#### **Individuals at the White House meeting of March 2, 2020.**

President Donald Trump, 2 years Fordham University and the 2 years Wharton School of the University of Pennsylvania, B.S. in Economics

Alexander Azar, Secretary of the U.S. Department of Health and Human Services, summa cum laude in government and economics from Dartmouth and J.D. from Yale University

Emma Walmsley , CEO of GlaxoSmithKline, MA in Classics and Modern Languages from Oxford University (Christ Church)

Anthony Fauci, M.D., Director of the NIAID of the NIH, College of the Holy Cross with a BA in classics and a MD from Cornell University graduating 1<sup>st</sup> in his class

Robert Redfield, M.D., Director of the CDC, graduated from Georgetown University’s College of Arts and Sciences with a BS and MD from Georgetown University School of Medicine

Daniel Menichella, CEO of CureVac, BA in economics from Harvard University and a MBA from University of North Carolina at Chapel Hill

John Shiver, PhD, Senior Vice President, Vaccines Global R&D at Sanofi Vaccines, BS in Chemistry/Mathematics, Woffard College and a PhD in Chemistry from the University of Florida

Leonard Schleifer, M.D., PhD, CEO Regeneron, BS at Cornell University and an MD-PhD from the University of Virginia

Stephane Bancel, CEO of Moderna, masters degrees from both CentraleSupélec of Paris-Saclay University (engineering) and the University of Minnesota (biological engineering) and an MBA from Harvard Business School

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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*  
**Prevention:** *Active Immunization:* Vaccines

Daniel O'Day, BS, MBA, Chairman and CEO of Gilead Sciences has a BS in biology from Georgetown University and an MBA from Columbia University in New York

Steven Hahn, M.D., Commissioner, U.S. Food and Drug Administration, BA in Biology from Rice University and MD from Temple University

Mikael Dolsten, M.D., Ph.D., Chief Scientific Officer of Pfizer, Ph.D. in tumor immunology and a MD from Lund University

Joseph Kim, Ph.D., Inovio Pharmaceuticals, BS degrees in Chemical Engineering and Economics from MIT, a Ph.D. in immunology from the University of Pennsylvania, and an MBA in finance from the Wharton School of Business, University of Pennsylvania

Paul Stoffels, M.D., Chief Scientific Officer of Johnson & Johnson, studied medicine at the University of Diepenbeek and the University of Antwerp in Belgium and Infectious Diseases and Tropical Medicine at the Institute of Tropical Medicine in Antwerp, Belgium.

Anne Schuchat, M.D., Principal Deputy Director of the CDC, Swarthmore College and MD Dartmouth Medical School

Stanley Erck, President and CEO of Novavax, undergraduate degree from the University of Illinois and MBA in economics and finance from the Booth School of Business, The University of Chicago

Ambassador Deborah Birx, M.D., U.S. Department of State, BS in chemistry from Houghton College and MD from Pennsylvania State University.

- 337)** 2020-03-05 Herper M, Feuerstein A: How blood plasma from recovered patients could help treat the new coronavirus. STATnews Mar 5, 2020, 1-7.  
<https://www.statnews.com/2020/03/05/how-blood-plasma-from-recovered-patients-could-help-treat-coronavirus/>

- 338)** 2020-03-09 Johns Hopkins University & Medicine Coronavirus Resource Center: First date documented by the Internet Archive (Wayback Machine: <https://archive.org/web/>) to have been published. <https://coronavirus.jhu.edu/map.html>

- 339)** 2020-03-09 U.S. Department of Health & Human Services, Centers for Medicare and Medicaid Services: Center for clinical standards and quality/quality, safety and oversight group. Ref: QSO-20-15 Hospital/CAH/EMTALA  
<https://www.cms.gov/files/document/qso-20-15-hospitalcahemtala.pdf>

- 340)** 2020-03-11 Downs Burger J: Novel coronavirus: EMTALA compliance for hospitals with dedicated emergency departments. Arnall, Golden, Gregory LLP  
<https://www.agg.com/news-insights/publications/novel-coronavirus-emtala-compliance-for-hospitals-with-dedicated-emergency-departments-2/>

On March 9, 2020, CMS issued a memorandum to State Survey Agency Directors regarding the implications of COVID-19 on providers' EMTALA obligations. In addition to confirming the

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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*  
**Prevention:** *Active Immunization:* Vaccines



recommendations in our March 6 Client Alert below, the CMS memorandum provides further guidance that hospitals with dedicated emergency departments should review. We highlight a few notable items below.

**Hospital Signage:** CMS emphasized that it is a violation of EMTALA for hospitals to use signage that presents barriers to individuals who are suspected of having COVID-19 from coming to the emergency room. However, use of signage designed to help direct individuals to various locations on the hospital property for their Medical Screening Exam – such as an alternative screening location – would be acceptable.

What if an individual who meets the screening criteria for suspected COVID-19 wants to leave the hospital against medical advice? Hospitals cannot prevent the individual from leaving against medical advice. However, State or local public health authorities may have such authority under State or local law. Hospitals should coordinate with their local authorities on the appropriate way to handle such situations.

How will CMS handle complaints about violations of EMTALA in connection with individuals presenting with symptoms of COVID-19? CMS states that it will consider the following (along with other factors) when making a determination of whether violations of EMTALA have occurred:

- The individual’s clinical condition at the time of presentation to the referring hospital and at the time of the transfer request;
- The capabilities of the referring hospital;
- The screening and treatment activities performed by the referring hospital for the individual;
- Whether the request for transfer was consistent with any nationally recognized guidelines in effect at the time of the transfer request for COVID-19 screening, assessment, including guidance about transfer for further assessment or treatment of suspected or confirmed COVID-19; and
- The capabilities of the recipient hospital and the recipient hospital’s capacity at the time of the transfer request.

What will CMS do if a hospital is not following nationally recognized guidelines regarding COVID-19 infection control processes? While EMTALA does not establish requirements for infection control practices, hospitals are expected to adhere to accepted standards of infection control practice and as part of the conditions of participation for Federal health care programs. CMS cautions that hospitals may be cited for deficiencies related to failure to follow accepted infection prevention and control standards of practice. As such, CMS strongly urges hospitals to follow CDC guidance related to COVID-19 infection control procedures. Hospitals should regularly check the official CDC website and consider signing up for the newsletter to receive weekly emails about COVID-19

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Novel coronavirus (“2019-nCoV”, also known as “SARS-CoV-2”) and the disease it causes – “coronavirus disease 2019” (abbreviated as “COVID-19”) has garnered significant public attention since being declared a Public Health Emergency of International Concern by the World Health Organization, and a public health emergency in the United States by the Department of Health and Human Services (“HHS”). Of particular significance to healthcare providers’ compliance efforts is whether the President’s observation and monitoring of the situation will culminate in a declaration by the President of a national emergency in connection with the incidences of novel coronavirus.

In the event of a declaration of a national emergency by the President, the requirements of the Emergency Medical Treatment and Labor Act (“EMTALA”) may be formally suspended. However, in the absence of such a declaration by the President and a formal suspension of EMTALA, hospitals are required to comply with EMTALA provisions and may be sanctioned for non-compliance. The Centers for Medicare and Medicaid Services (“CMS”) has made recommendations regarding the ways in which hospital emergency departments may take adequate precautions in circumstances like these, while also complying with EMTALA mandates in the absence of a formal suspension. We outline these frameworks in further detail below.

#### What is EMTALA?

EMTALA is a federal law that requires all Medicare-participating hospitals with a dedicated emergency department to take certain actions when any individual comes to the emergency department and requests an examination or treatment of a medical condition, or when such a request is made on the individual’s behalf, regardless of the individual’s ability to pay. EMTALA was enacted to prevent hospitals from “dumping” patients because the patients could not pay for treatment, or because of other discriminatory purposes. If a hospital is subject to EMTALA, then it must perform an appropriate medical screening exam (“MSE”) on the individual to determine if an emergency medical condition (“EMC”) exists. The content of the MSE may vary based on the individual’s presenting signs and symptoms, so long as the MSE is sufficient to rule out that an EMC exists. The MSE must be performed by qualified personnel, including a physician, physician assistant, nurse practitioner, or registered nurse who is trained to perform MSEs and who is acting within their state’s scope of practice. If an EMC does exist, then the hospital must treat and stabilize the EMC within its capabilities to do so, or alternatively, transfer the individual to a hospital that has the capability and capacity to stabilize the EMC. If an EMC does not exist, then the hospital’s obligations with regard to EMTALA end.

#### When Are a Hospital’s EMTALA Obligations Suspended During a National Emergency?

It seems to be a common misconception that when a state’s governor has declared a state of emergency in response to a disease outbreak (whether COVID-19, the flu, or otherwise), a hospital’s MSE and stabilization obligations under EMTALA have been suspended. However, in such situations, a well-meaning hospital can find itself in violation of EMTALA.

In order for a hospital’s MSE and stabilization obligations to be suspended, the federal government must first take four formal actions under Section 1135 of the Social Security Act (“Section 1135”):

1. The President, and not the state’s governor, must have declared an emergency or a disaster under either the Stafford Act or the National Emergencies Act;
2. The Secretary of Health and Human Services (the “Secretary”) must have declared a public health emergency;
3. The Secretary must have invoked his or her waiver authority, which includes giving Congress 48 hours’ advance notice; and
4. The Secretary must issue a waiver that would cover the hospital and includes a specific waiver of the EMTALA requirements.

Then, the hospital’s state must have formally activated its emergency or pandemic preparedness plan and any redirection or transfer of individuals must be consistent with this plan. Additionally, the EMTALA waiver will not apply to a hospital that has not activated its own disaster protocol.

When such a waiver is issued, CMS is to provide notice to covered hospitals through its Regional Offices or State Survey Agencies. When an EMTALA waiver is issued for a public health emergency caused by a pandemic infectious disease, such as novel coronavirus, the EMTALA waiver remains in place until the Secretary terminates the declaration of the public health emergency.

#### What Obligations under EMTALA May be Suspended by a Waiver?

As alluded to above, Section 1135 allows the Secretary to waive the sanctions associated with a hospital for redirecting an individual to an alternative location for the MSE pursuant to a state emergency or pandemic preparedness plan that would otherwise not be allowed under EMTALA. The Secretary may also waive sanctions for a hospital's inappropriate transfer if the transfer was necessitated by the circumstances of the declared emergency. This typically allows a hospital to avoid sanctions when it transfers a patient before the EMC is stabilized. However, a hospital may not discriminate among individuals based on their ability to pay or their payor source while under a waiver. Sanctions for all other EMTALA requirements may not be waived. It is also important to note that a Section 1135 waiver does not, in and of itself, relieve the hospital from any obligations under state or local laws. Note that if a waiver is issued, it only waives the sanctions applicable to the hospital under EMTALA. Therefore, if an individual is harmed by a hospital's negligent transfer or redirection performed under a waiver, then the hospital may be liable to the individual for that harm.

#### Can a Hospital Request a Waiver if One Has Not Been Issued?

Yes. If an EMTALA waiver has not yet been issued that covers a hospital, then the hospital may request a waiver under Section 1135. Before CMS will consider a waiver request, the federal government must have performed the first three formal actions outlined above. Furthermore, the Secretary must have delegated his or her decision-making regarding EMTALA to CMS. The hospital, or the hospital's representative, typically makes the waiver request to the CMS Regional Office for the region in which the hospital is located.

#### What are a Hospital's Options if a Waiver is Not Granted?

If a waiver is not granted, hospitals have a couple of options to separate patients presenting with symptoms of COVID-19 in the emergency department, while continuing to meet EMTALA mandates.

Option 1: Set Up On-Campus Alternative Screening Sites. A hospital is not required to perform the MSE within the emergency department itself. A hospital could instead set up alternative sites on its campus to perform certain MSEs. The patient would need to be logged into the emergency department before being redirected to the alternative site, but this process could take place outside of the entrance to the emergency department. CMS recommends that if a hospital implements such a process, then the persons redirecting patients to the alternative site should be qualified to recognize patients who are obviously in need of emergency treatment (for example, a registered nurse). The MSEs performed at the alternative site must meet all the requirements for MSEs required by law.

Option 2: Set Up Off-Campus Alternative Screening Sites. A hospital may set up a screening site that is not on its campus, as long as the location remains under the hospital's control. This arrangement makes compliance with EMTALA somewhat riskier than the first option. The hospital could not, for instance, redirect individuals who have already come to the emergency department to the off-campus location. The hospital could prospectively encourage the general public to go to the off-campus location for screenings related to COVID-19 and/or influenza, and could publically hold out that the location serves a screening center for that specific purpose. In doing so, however, the hospital could not hold the location out as a place that provides care or screening for EMCs in general on an urgent, unscheduled basis. As long as the off-

campus site is not itself a dedicated emergency department, then EMTALA does not apply to the visit. Significantly, the site should still be staffed by medical personnel qualified to evaluate individuals presenting with symptoms of COVID-19 and/or flu-like symptoms.

## Conclusion

Certain EMTALA obligations may be waived during a national emergency when the federal government takes formal actions specified in the Social Security Act. This waiver only applies to hospitals that (1) are located in states that have formally activated their emergency or pandemic preparedness plan and (2) have activated their own disaster protocol. Even under a waiver, hospitals must continue to meet all non-waived EMTALA obligations. If a waiver has not been issued, then a hospital may apply to CMS for a waiver. If a waiver is not granted, then the hospital may redirect individuals to an alternative screening site located on the hospital's campus so long as all EMTALA requirements are met. A hospital may also set up alternative screening sites off of its campus; however, patients who have already presented to the emergency department may not be redirected to these sites.

If you have any questions about whether your emergency department's operational plan or disaster protocol is compliant with EMTALA or would like assistance requesting a Section 1135 waiver, please contact [Jennifer Bugar](#), [Ryan Kerr](#) or [Nirouz Elhammali](#).

## Summary and Practical Tips for EMTALA Compliance

- The federal government can waive certain EMTALA requirements during a declared public health emergency.
- Federal and state governments and the hospital must take specific formal actions before these requirements are waived.
- The Secretary of HHS may only waive the sanctions associated with redirecting individuals for their medical screening exam and for transfer that would otherwise be inappropriate under EMTALA.
- If an individual is redirected for a medical screening exam or is inappropriately transferred under a waiver, then the redirection or transfer must not have been made for a discriminatory purpose.
- A hospital must continue to meet all other EMTALA obligations.
- The hospital remains liable in legal actions by individuals who are harmed by redirection or transfers made under a waiver.
- A hospital can request a waiver from CMS if one has not been granted.
- Without a waiver, a hospital may redirect patients for a COVID-19 or other influenza-like illness screening to an alternative on-campus location so long as the hospital's EMTALA obligations continue to be met
- Without a waiver, a hospital may make off-campus locations available for such illness screenings so long as the location is under the control of the hospital and individuals who come to the emergency department are not redirected to these locations.

**341)** 2020-03-13 Casadevall A, Pirofski L: The convalescent sera option for containing COVID-19. [jci.org, Journal of Clinical Investigation 130 (4); April 2020: 1545-1548]. <https://www.jci.org/articles/view/138003>. <https://www.jci.org/articles/view/138003/pdf>

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*A general principle of passive antibody therapy is that it is more effective when used for prophylaxis than for treatment of disease. When used for therapy, antibody is most effective when administered shortly after the onset of symptoms. The reason for temporal variation in efficacy is not well understood but could reflect that passive antibody works by neutralizing the initial inoculum, which is likely to be much smaller than that of established disease (5). Another explanation is that antibody works by modifying the inflammatory response, which is also more easily achieved during the initial immune response, which is also more easily achieved during the initial immune response, a stage that may be asymptomatic (6). ...*

*For passive antibody therapy to be effective, a sufficient amount of antibody must be administered. When given to a susceptible person, this antibody will circulate in the blood, reach tissues, and provide protective against infection. Depending on the antibody amount and composition, the protection conferred by the transferred immunoglobulin can last from weeks to months.....*

**Figure 1. Schematic of the use of convalescent sera for COVID-19.** *An individual who is sick with COVID-19 and recovers has blood drawn and screened for virus-neutralizing antibodies. Following identification of those with high titers of neutralizing antibody, serum containing these virus-neutralizing antibodies can be administered in a prophylactic manner to prevent infections in high-risk cases, such as vulnerable individuals with underlying medical conditions, health care providers, and individuals with exposure to confirmed cases of COVID-19. Additionally, convalescent serum could potentially be used in individuals with clinical disease to reduce symptoms and mortality. The efficacy of these approaches is not known, but historical experience suggests that convalescent sera may be more effective in preventing disease than the treatment of established disease.*

- 342)** 2020-03-13 Hixenbaugh M: Doctors push for treatment of coronavirus with blood from recovered patients. NBC News, March 12, 2020. <https://www.nbcnews.com/health/health-care/doctors-push-treatment-coronavirus-blood-recovered-patients-n1158476>

*When Casadevall learned in December that a new coronavirus was spreading rapidly in China, he started telling colleagues that it might be time to revive the antiquate treatment.*

*"I'm an infectious disease doctor who is interested in history," Casadevall said. "I knew the history of what was done in the early 20<sup>th</sup> century with epidemics. The didn't have vaccines then, they didn't have any drugs then – just like the situation we face now. But physicians then knew that ,for certain conditions, you could take the blood of the immune and use it to prevent disease or treat those who became ill."*

*In a paper published Friday in the Journal of Clinical Investigation, Casadevall and a colleague, Dr. Liise-anne Pirofski argued that collecting blood serum or plasma from previously infected people might be the best hope for treating severe cases of COVID-19, the disease caused by the virus, at least until a better treatment can be developed.*

- 343)** 2020-03-13 Trump DJ: Proclamation on declaring a national emergency concerning the novel coronavirus disease (COVID-19) outbreak. The White House. <https://trumpwhitehouse.archives.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/>

*Section 1. Emergency Authority. The Secretary of HHS may exercise the authority under section 1135 of the SSA to temporarily waive or modify certain requirements of the Medicare, Medicaid, and State Children's Health Insurance programs and of the Health Insurance Portability and*



*Accountability Act Privacy Rule throughout the duration of the public health emergency declared in response to the COVID-19 outbreak.*

**344)** 2020-03-13 Azar AM: Waiver or modification of requirements under section 1135 of the Social Security Act.

[www.phe.gov/emergency/news/healthactions/section1135/Pages/covid19-13March20.aspx](https://www.phe.gov/emergency/news/healthactions/section1135/Pages/covid19-13March20.aspx)

*de facto*, I allege that the interpretation of this document became the justification of abridgement of individual American rights to *Passive Immunization* and the antiviral drug Remdesivir, guaranteed under EMTALA (the Emergency Medical Treatment and Labor Act of COBRA, Consolidated Omnibus Budget Act of 1986, PL-99-272), and the Right to Tray Act of 2018, PL-115-176. Copied verbatim:

## Waiver or Modification of Requirements Under Section 1135 of the Social Security Act

March 13, 2020

1. Pursuant to Section 1135(b) of the Social Security Act (the Act) (42 U.S.C. § 1320b-5), I, Alex M. Azar II, Secretary of Health and Human Services, hereby waive or modify the following requirements of titles XVIII, XIX, and XXI of the Act and regulations thereunder, and the following requirements of Title XI of the Act, and regulations thereunder, insofar as they relate to Titles XVIII, XIX, and XXI of the Act, but in each case, only to the extent necessary, as determined by the Centers for Medicare & Medicaid Services, to ensure that sufficient health care items and services are available to meet the needs of individuals enrolled in the Medicare, Medicaid and CHIP programs and to ensure that health care providers that furnish such items and services in good faith, but are unable to comply with one or more of these requirements as a result of the consequences of the 2019 Novel Coronavirus (previously referred to as 2019-nCoV, now as COVID-19) pandemic, may be reimbursed for such items and services and exempted from sanctions for such noncompliance, absent any determination of fraud or abuse:
  - a. Certain conditions of participation, certification requirements, program participation or similar requirements for individual health care providers or types of health care providers, including as applicable, a hospital or other provider of services, a physician or other health care practitioner or professional, a health care facility, or a supplier of health care items or services, and pre-approval requirements.
  - b. Requirements that physicians or other health care professionals hold licenses in the State in which they provide services, if they have an equivalent license from another State (and are not affirmatively barred from practice in that State or any State a part of which is included in the emergency area).
  - c. Sanctions under section 1867 of the Act (the Emergency Medical Treatment and Labor Act, or EMTALA) for the direction or relocation of an individual to another location to receive medical screening pursuant to an appropriate state emergency preparedness plan or for the transfer of an individual who has not been stabilized if the transfer is necessitated by the circumstances of the declared Federal public health emergency for the COVID-19 pandemic.
  - d. Sanctions under section 1877(g) (relating to limitations on physician referral) under such conditions and in such circumstances as the Centers for Medicare & Medicaid Services determines appropriate.
  - e. Limitations on payments under section 1851(i) of the Act for health care items and services furnished to individuals enrolled in a Medicare Advantage plan by health care professionals or facilities not included in the plan's network.

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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*  
**Prevention:** *Active Immunization:* Vaccines

2. Pursuant to Section 1135(b)(7) of the Act, I hereby waive sanctions and penalties arising from noncompliance with the following provisions of the HIPAA privacy regulations: (a) the requirements to obtain a patient's agreement to speak with family members or friends or to honor a patient's request to opt out of the facility directory (as set forth in 45 C.F.R. § 164.510); (b) the requirement to distribute a notice of privacy practices (as set forth in 45 C.F.R. § 164.520); and (c) the patient's right to request privacy restrictions or confidential communications (as set forth in 45 C.F.R. § 164.522); but in each case, only with respect to hospitals in the designated geographic area that have hospital disaster protocols in operation during the time the waiver is in effect.
3. Pursuant to Section 1135(b)(5), I also hereby modify deadlines and timetables and for the performance of required activities, but only to the extent necessary, as determined by the Centers for Medicare & Medicaid Services, to ensure that sufficient health care items and services are available to meet the needs of individuals enrolled in the Medicare, Medicaid and CHIP programs and to ensure that health care providers that furnish such items and services in good faith, but are unable to comply with one or more of these requirements as a result of the COVID-19 pandemic, may be reimbursed for such items and services and exempted from sanctions for such noncompliance, absent any determination of fraud or abuse.

These waivers and modifications will become effective at 6:00 P.M. Eastern Standard Time on March 15, 2020, but will have retroactive effect to March 1, 2020, nationwide, and continue through the period described in Section 1135(e). Notwithstanding the foregoing, the waivers described in paragraph 2 above are in effect for a period of time not to exceed 72 hours from implementation of a hospital disaster protocol but not beyond the period described in Section 1135(e). The waivers described in paragraphs 1(c) and 2 above are not effective with respect to any action taken thereunder that discriminates among individuals on the basis of their source of payment or their ability to pay.

The waivers and modifications described herein apply in the geographic area covered by the President's proclamation, pursuant to the National Emergencies Act, on March 13, 2020, that the COVID-19 outbreak in the United States constitutes a national emergency; and my January 31, 2020, determination, pursuant to section 319 of the Public Health Service Act, that a public health emergency as a result confirmed cases of 2019 Novel Coronavirus, exists and has existed since January 27, 2020, nationwide.

3/13/2020

/s/

Date

Alex M. Azar II

**345)** 2020-03-14 Zhihuan L: China sending medical team to help Italy contain virus.  
ChinaDaily 14 March 2020: 1-2.  
<https://www.chinadaily.com.cn/a/202003/14/WS5e6bd352a31012821727f096.html>

**346)** 2020-03-16 Brown BL, McCullough J: Treatment for emerging viruses: Convalescent plasma and COVID-19. Transfusion and Apheresis Science 59 (2020) 102790 : 1-5.  
<https://www.medrxiv.org/content/10.1101/2020.03.16.20036145v1.full.pdf>

2020-04-14: accepted for publication:

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7194745/pdf/main.pdf>

#### ABSTRACT

Use of convalescent plasma transfusions could be of great value in the current pandemic of coronavirus disease (COVID-19), given the lack of specific preventative and therapeutic options. This convalescent plasma therapy is of particular interest when a vaccine or specific

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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*  
**Prevention:** *Active Immunization:* Vaccines

therapy is not yet available for emerging viruses, such as severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), which causes COVID-19. This report summarizes existing literature around convalescent plasma as a therapeutic option for COVID-19. It also includes recommendations for establishing a convalescent plasma program, enhancement considerations for convalescent plasma, and considerations around pathogen reduction treatment of convalescent plasma. Time is of the essence to set up protocols for collection, preparation, and administration of apheresis-collected convalescent plasma in response to the current pandemic. The immediate use of convalescent plasma provides prompt availability of a promising treatment while specific vaccines and treatments are evaluated and brought to scale. Further development of improved convalescent plasma, vaccines and other therapeutics depends on quick generation of additional data on pathogenesis and immune response. Additionally, given the lack of information around the natural history of this disease, PRT should be considered to add a layer of safety to protect recipients of convalescent plasma.

- 347)** 2020-03-17 Azar A: Declaration under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19. Federal Register, 3/17/2020. <https://www.federalregister.gov/documents/2020/03/17/2020-05484/declaration-under-the-public-readiness-and-emergency-preparedness-act-for-medical-countermeasures>
- 348)** 2020-03-17 Regeneron: Regeneron announces important advances in novel COVID-19 antibody program. <https://investor.regeneron.com/news-releases/news-release-details/regeneron-announces-important-advances-novel-covid-19-antibody>
- 349)** 2020-03-18 Duan K, Liu Bende, Li Cesheng, Zhang H, Yu T, Qu J, Zhou M, Chen L, Meng S, Hu Y, Peng C, Yuan M, Huang J, Wang Z, Yu J, Gao X, Wang D, Yu X, Li L, Zhang J, Wu X, Li B, Xu Y, Chen W, Peng Y, Hu Y, Lin L, Liu X, Huang S, Zhou Z, Zhang L, Wang Y, Zhang Z, Deng K, Xia Z, Gong Q, Zhang W, Zheng X, Liu Y, Yang H, Zhou D, Yu D, Hou J, Shi Z, Chen S, Chen Z, Zhang X, Yang X: Effectiveness of convalescent plasma therapy in severe COVID-19 patients. 18 March 2020; PNAS (Proceedings of the National Academy of Sciences of the United States of America) : 1-22. <https://www.pnas.org/content/pnas/117/17/9490.full.pdf>

Currently, there are no approved specific antiviral agents for novel coronavirus disease 2019 (COVID-19). In this study, 10 severe patients confirmed by real-time viral RNA test were enrolled prospectively. One dose of 200 mL of convalescent plasma (CP) derived from recently recovered donors with the neutralizing antibody titers above 1:640 was transfused to the patients as an addition to maximal supportive care and antiviral agents. The primary endpoint was the safety of CP transfusion. The second endpoints were the improvement of clinical symptoms and laboratory parameters within 3 d after CP transfusion. The median time from onset of illness to CP transfusion was 16.5 d. After CP transfusion, the level of neutralizing antibody increased rapidly up to 1:640 in five cases, while that of the other four cases maintained at a high level (1:640). The clinical symptoms were significantly improved along with increase of oxyhemoglobin saturation within 3 d. Several parameters tended to improve as compared to pretransfusion, including increased lymphocyte counts ( $0.65 \times 10^9 /L$  vs.  $0.76 \times 10^9 /L$ ) and decreased C-reactive protein (55.98 mg/L vs. 18.13 mg/L). Radiological examinations showed varying degrees of absorption of lung lesions within 7 d. The viral load was undetectable after transfusion in seven patients who had previous viremia. No severe adverse effects were observed. This study showed CP therapy was well tolerated and could potentially improve the clinical outcomes through neutralizing viremia in severe COVID-19 cases. The optimal dose and time point, as well as the clinical benefit of CP therapy, needs further investigation in larger well-controlled trials.

- 350) 2020-03-18 Trump DJ: Declaring a national emergency concerning the novel coronavirus disease (COVID-19) outbreak.  
<https://www.federalregister.gov/documents/2020/03/18/2020-05794/declaring-a-national-emergency-concerning-the-novel-coronavirus-disease-covid-19-outbreak>
- 351) 2020-03-18 Pharmaceutical Technology: Regeneron identifies several antibodies against Covid-19. <https://www.pharmaceutical-technology.com/news/regeneron-covid-19-antibodies/>
- 352) 2020-03-19 Adams J: PSA, If You Are Sick. March 19, 2020.  
<https://www.facebook.com/WhiteHouse/videos/psa-if-you-are-sick/196091611816606/>

As the Nation's doctor, I often get asked: What should I do if I think I might have coronavirus? Well, it is important to know the symptoms--they include: fever, cough, and shortness of breath. If you are having these symptoms or worry you might have coronavirus, please call your healthcare provider. **We don't want you to go into the ER or the doctor's office without talking to them first because you might spread coronavirus to someone else.** They will help you think through and learn how to react including figuring out where to go to get tested if necessary.

Dr. Jerome Adams, PSA, If You Are Sick, March 19, 2020.

This PSA makes the assumption that American's have an established PCP's whom they can call but that is not truth:

Fong M: Nearly 1 in 5 Americans haven't seen a doctor in over five years. Onlinedoctor April 14, 2021. <https://www.onlinedoctor.com/nearly-1-in-5-americans-havent-seen-a-doctor-in-over-five-years/>

CDC: Percentage of having a wellness visit in past 12 months for adults aged 18 and over, United States, 2019. CDC, Centers for Disease Control and Prevention, National Center for Health Statistics: Interactive Summary Health Statistics for Adults—2019.  
[https://wwwn.cdc.gov/NHISDataQueryTool/SHS\\_adult/index.html](https://wwwn.cdc.gov/NHISDataQueryTool/SHS_adult/index.html)

CDC: National Ambulatory Medical Care Survey: 2018 National Summary Tables [https://www.cdc.gov/nchs/data/ahcd/namcs\\_summary/2018-namcs-web-tables-508.pdf](https://www.cdc.gov/nchs/data/ahcd/namcs_summary/2018-namcs-web-tables-508.pdf)

- 353) 2020-03-19 Simpson BW: COVID-19's stop-gap solution until vaccines and antivirals are ready. Global Health NOW, Johns Hopkins Bloomberg School of Public Health  
<https://www.globalhealthnow.org/2020-03/covid-19s-stop-gap-solution-until-vaccines-and-antivirals-are-ready>

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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*  
**Prevention:** *Active Immunization:* Vaccines

***How can plasma be useful against the novel coronavirus?***

*When you recover from many viral diseases, you have in your blood what are called neutralizing antibodies. These are antibodies that kill the virus. Once you recover, the plasma be taken from donors. It's very safe. It's the same thing as using a blood donation except they don't take the red blood cells, they take the liquid. They take the plasma. It is itself a drug...it can be used for prevention of infection for people who are being exposed or it could be used for therapy for those who are sick.*

*It's not a vaccine. Think about it as the administration of a protein, it's a liquid that is given to people that gives them immunity.*

***Right. Because the vaccine would provoke the recipient's antibodies. You'll have the antibodies, but they won't be your antibodies—though it'll do the same thing.***  
*Right.*

***And if somebody is already sick, can the plasma help them?***  
*Yes, it can be used for prevention or a treatment.*

***This strategy is already being used in China?***  
*Yes, in fact, the Chinese sent 90 tons of plasma to Italy.*

- 354)** 2020-03-20 Zhou G, Chen S, Chen Z: Advances in COVID-19: the virus, the pathogenesis, and evidence-based control and therapeutic strategies.  
[https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7171433/pdf/11684\\_2020\\_Article\\_773.pdf](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7171433/pdf/11684_2020_Article_773.pdf)
- 355)** 2020-03-20 Healy M: How the blood of coronavirus survivors may protect others from COVID-19. Los Angeles Times 20 March 2020, 1/8.  
<https://www.latimes.com/science/story/2020-03-20/how-blood-from-people-who-survived-covid-19>
- 356)** 2020-03-21 Guo L, Ren L, Yang S, Xiao M, Chang D, Yang F, Dela Cruz CS, Wang Y, Wu Ch, Xiao Y, Zhang L, Han L, Dang S, Xu Y, Yang QW, Xu SY, Zhu HD, Xu YC, Ji Q, Sharma L, Wang L, Wang J: Profiling early humoral response to diagnose novel coronavirus disease (COVID-19). Clin Infect Dis XX XXXX 2020; XX: 1-8.  
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7184472/pdf/ciaa310.pdf> ; Clin Infect Dis 2020 Jul 28; 71(15): 778-785. <https://pubmed.ncbi.nlm.nih.gov/32198501/>
- 357)** 2020-03-23 Good/Shutterstock M: World Health Organization warns against untested drugs for COVID-19. Biospace <https://www.biospace.com/article/world-health-organization-warns-against-untested-drugs-for-covid-19/>
- 358)** 2020-03-23 Duan K, Liu B, Li C, Zhang H, Yu T, Qu J, Zhou M, *et. al.*: The feasibility of convalescent plasma therapy in severe COVID-19 patient: a pilot study. medRxiv Mar 23, 2020; 1 – 21. <https://www.medrxiv.org/content/10.1101/2020.03.16.20036145v1.full.pdf>
- 359)** 2020-03-23 U.S. Food and Drug Administration: Emergency Use Authorization. Emergency Use Authorization (EUA) information, and list of all current EUAs.



<https://web.archive.org/web/20200324160355/https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>

360) 2020-03-23 Bhandari T: Possible COVID-19 treatment: transfusion of antibodies from recovered patients' blood—Century-old idea applied to modern pandemic.  
<https://medicine.wustl.edu/news/possible-covid-19-treatment-transfusion-of-antibodies-from-recovered-patients-blood/>

361) 2020-03-24 Scrip Team: Coronavirus Update: South Korea's Celltrion progresses antibody, Yancopoulos: 'The World is Counting on Us' – Antibody Therapies could ease huge burden on emergency care. Informa Pharma Intelligence  
<https://scrip.pharmaintelligence.informa.com/SC141901/Coronavirus-Update-South-Koreas-Celltrion-Progresses-Antibody-Yancopoulos-The-World-Is-Counting-On-Us>

362) **2020-03-24 U.S. Food and Drug Administration:  
Investigational COVID-19 Convalescent Plasma – Emergency  
INDs, March 24, 2020.**

[https://notifiylibrary.org/sites/default/files/Investigational%20COVID-19%20Convalescent%20Plasma%20-%20Emergency%20INDs%20\\_%20FDA.pdf](https://notifiylibrary.org/sites/default/files/Investigational%20COVID-19%20Convalescent%20Plasma%20-%20Emergency%20INDs%20_%20FDA.pdf)

• **Eligible patients for use under expanded access provisions:**

- Must have laboratory confirmed COVID-19
- Must have severe or immediately life-threatening COVID-19, for example:<sup>1</sup>
  - Severe disease is defined as:
    - dyspnea,
    - respiratory frequency  $\geq 30$ /min,
    - blood oxygen saturation  $\leq 93\%$ ,
    - partial pressure of arterial oxygen to fraction of inspired oxygen ratio  $< 300$ , and/or
    - lung infiltrates  $> 50\%$  within 24 to 48 hours
  - Life-threatening disease is defined as:
    - respiratory failure,
    - septic shock, and/or

<https://www.fda.gov/vaccines-blood-biologics/investigational-new-drug-ind-or-device-exemption-ide-process-cber/investigational-covid-19-convale...> 2/3

27/3/2020

Investigational COVID-19 Convalescent Plasma - Emergency INDs | FDA

- multiple organ dysfunction or failure

- Must provide informed consent

<sup>1</sup>Wu Z, McGoogan JM. Characteristics of and Important Lessons From the Coronavirus Disease 2019 (COVID-19) Outbreak in China: Summary of a Report of 72 314 Cases From the Chinese Center for Disease Control and Prevention. *JAMA*. Published online February 24, 2020. doi:10.1001/jama.2020.2648

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**Treatment:** Passive Immunization: COVID-19 Convalescent Plasma and Antibodies and Antivirals

**Prevention:** Active Immunization: Vaccines

**NO WHERE in the aforementioned reference #1 by Wu and McGoogan upon which officially the U.S. FDA based the *Eligibility Criteria* for administration of COVID-19 Convalescent Plasma from March 24, 2020 to September 2, 2020 is “CONVALESCENT”, “PLASMA”, “ELIGIBILITY” or “CRITERIA” mentioned even once !!!!**

2020-03-24 Investigational COVID-19 Convalescent Plasma – Emergency INDs. (This is the NATAP Verbatim internet copy of reference 28 in its entirety that I have copied and pasted verbatim to follow from [https://natap.org/2020/COVID/032320\\_39.htm](https://natap.org/2020/COVID/032320_39.htm) as this is an original copy I can find on the Internet which is of the FDA’s directive of March 24, 2020 that directed all the *misdirection based on only one reference #1 by Zunyou Wu, M.D., PhD, Jennifer M. McGoogan, PhD which never mentions COVID-19 Convalescent Plasma nor recommends* the eligibility criteria justifying the FDA authorizations of COVID-19 Convalescent Plasma (CCP), and EUAs that were to follow in the next 10 months.)

**PLEASE NOTE THAT WEB SITE REFERENCED JUST BELOW MARCH 24, 2020**  
<https://www.fda.gov/vaccines-blood-biologics/investigational-new-drug-ind-or-device-exemption-ide-process-cber/investigational-covid-19-convalescent-plasma-emergency-ind> IS A HYPERLINK THAT BECAUSE OF THE FDA OVERWRITING PRACTICES AS PERMITTED BY THAT WHICH WAS PUBLISHED IN THE *FEDERAL REGISTER* on March 25, 2020 now points *ex post facto* to the future FDA website: Recommendations for Investigational COVID-19 Convalescent Plasma, February 11, 2021, and then with each overwrite *ad infinitum*. (One can trace back the referenced website with modifications using the *Internet Archive (Wayback Machine -- https://archive.org/web/ )* to April 8, 2020. The FDA version of the verbatim document below must have been referenced between March 24, 2020 to ~April 8, 2020 was electronically replaced so that media articles (listed below) referencing the March 24, 2020 announcement *ex post facto* references to April 8, 2020.

*I, therefore, allege that there was **Blatant Misdirection** of the official FDA documentation of March 24, 2020 in which the *Eligibility Criteria* is wrongly attributed to reference #1 which initiated the administration of CCP TO ONLY EXTREMELY ILL INDIVIDUAL PATIENTS AT THE **WRONG TIME** (not during the early viremic phase or prophylactically) which was probably a **Federal Criminal Offense** by someone in the FDA, Department of Health and Human Services, and/or *The White House*.*

I allege, on behalf of the American people, this misdirection of official federal FDA documentation facilitated: 1) misdirected CCP application at an inappropriate (wrong) late-in-time in the course of the disease in >700,000 individuals having contracted COVID-19 and having developed life-threatening systemic complications (e.g., bilateral pneumonitis, kidney failure, etc.; 2) promoted nonsensical, inappropriate medical research/NIH ClinicalTrials ( <https://www.clinicaltrials.gov/> of CCP at the wrong administration time); 3) promoted violation of PL-115-176--*The Right to Try Law*-- by promoting NON Completion of Phase I Studies; 4) promoted CCP application late in the individual’s COVID-19 disease (which is the **WRONG TIME** to administer *Passive Immunization*); 5) led to the *de facto* discrediting of *Passive Immunization* as a treatment; 6) promoted *de facto* physician abandonment of their individual COVID-19 positive patients early in the course of the individual’s disease (viremic phase); and 7) inadvertently led to greater than a half-of-a-million American deaths!

Below, copied and pasted *verbatim* from the National AIDS Treatment Advocacy Project (NATAP) [https://natap.org/2020/COVID/032320\\_39.htm](https://natap.org/2020/COVID/032320_39.htm) is the original NATAP copy found of the FDA’s directive of March 24, 2020 that directed the *misdirection* regarding the eligibility criteria, FDA authorizations of COVID-19 Convalescent Plasma (CCP), and EUAs that were to follow for the next 10 months.

### **Investigational COVID-19 Convalescent Plasma - Emergency INDs**

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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*  
**Prevention:** *Active Immunization:* Vaccines

March 24, 2020

<https://www.fda.gov/vaccines-blood-biologics/investigational-new-drug-ind-or-device-exemption-ide-process-cber/investigational-covid-19-convalescent-plasma-emergency-inds>

The Food and Drug Administration (FDA or Agency) plays a critical role in protecting the United States from public health threats including the Coronavirus Disease 2019 (COVID-19) pandemic. FDA is committed to doing everything we can to provide timely response efforts to this pandemic and facilitate access to investigational drugs for use in patients with serious or immediately life-threatening COVID-19 infections.

One investigational treatment being explored for COVID-19 involves the use of convalescent plasma collected from recovered COVID-19 patients. It is possible that convalescent plasma that contains antibodies to SARS-CoV-2 (the virus that causes COVID-19) might be effective against the infection. Use of convalescent plasma has been studied in outbreaks of other respiratory infections, including the 2009-2010 H1N1 influenza virus pandemic, 2003 SARS-CoV-1 epidemic, and the 2012 MERS-CoV epidemic. Although promising, convalescent plasma has not been shown to be effective in every disease studied. It is therefore important to determine through clinical trials, before routinely administering convalescent plasma to patients with COVID-19, that it is safe and effective to do so. Investigators wishing to study the use of convalescent plasma are encouraged to submit requests to FDA for investigational use under the traditional IND regulatory pathway (21 CFR 312).

Although participation in clinical trials is one way for patients to obtain access to convalescent plasma, these may not be readily available to all patients in potential need. Therefore, given the public health emergency that the expanding COVID-19 outbreak presents, while clinical trials are being conducted, FDA is facilitating access to COVID-19 convalescent plasma for use in patients with serious or immediately life-threatening COVID-19 infections through the process of single patient emergency Investigational New Drug Applications (eINDs) for Individual patients under 21 CFR 312.310. This process allows the use of an investigational drug for the treatment of an individual patient by a licensed physician upon FDA authorization. This does not include the use of COVID-19 convalescent plasma for the prevention of infection.

**Healthcare providers interested in the emergency use of investigational COVID-19 convalescent plasma under a single patient emergency IND should consider the following:**

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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*  
**Prevention:** *Active Immunization:* Vaccines

#### • COVID 19 Convalescent Plasma

COVID-19 convalescent plasma must only be collected from recovered individuals if they are eligible to donate blood (21 CFR 630.10, 21 CFR 630.15). Required testing must be performed (21 CFR 610.40) and the donation must be found suitable (21 CFR 630.30).

Additional considerations for donor eligibility should be addressed, as follows:

- Prior diagnosis of COVID-19 documented by a laboratory test
- Complete resolution of symptoms at least 14 days prior to donation
- Female donors negative for HLA antibodies or male donors
- Negative results for COVID-19 either from one or more nasopharyngeal swab specimens or by a molecular diagnostic test from blood. A partial list of available tests can be accessed at <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations>.
- Defined SARS-CoV-2 neutralizing antibody titers, if testing can be conducted (e.g., optimally greater than 1:320)

The container label of COVID-19 convalescent plasma units must include the following statement, "Caution: New Drug-- Limited by Federal (or United States) law to investigational use." (21 CFR 312.6 (a))

#### • Eligible patients for use under expanded access provisions:

- Must have laboratory confirmed COVID-19
- Must have severe or immediately life-threatening COVID-19, for example:<sup>1</sup>
  - Severe disease is defined as:
    - dyspnea,
    - respiratory frequency  $\geq 30/\text{min}$ ,
    - blood oxygen saturation  $\leq 93\%$ ,
    - partial pressure of arterial oxygen to fraction of inspired oxygen ratio  $< 300$ , and/or
    - lung infiltrates  $> 50\%$  within 24 to 48 hours
  - Life-threatening disease is defined as:
    - respiratory failure,
    - septic shock, and/or
    - multiple organ dysfunction or failure
- Must provide informed consent

#### How to obtain authorization for use of COVID-19 convalescent plasma

- For request that are not highly time sensitive (response from FDA provided within 4 to 8 hours), the requesting physician may contact FDA by completing form 3926 (<https://www.fda.gov/media/98616/download>) and submitting the form by email to [CBER\\_eIND\\_COVID-19@FDA.HHS.gov](mailto:CBER_eIND_COVID-19@FDA.HHS.gov).
  - The completed form should include a brief clinical history of the patient, including: diagnosis, current therapy, and rationale for requesting the proposed investigational treatment in order to meet the expanded access use requirements of 21 CFR 312.305 and 312.310.
  - The form should include information regarding where the COVID-19 convalescent plasma will be obtained.
  - Providers should complete the form to the extent possible, and FDA will work with the provider if additional information is required.
  - FDA will review the request and, upon approval, FDA will send the requesting physician a confirmatory email that includes the emergency IND number.
- In the event of an emergency that is highly time sensitive (response required in less than 4 hours) or where the provider is unable to complete and submit form 3926 due to extenuating circumstances, the provider may contact FDA's Office of Emergency Operations at 1-866-300-4374 to seek verbal authorization.
  - If verbal authorization is given, the requestor must agree to submit an expanded access application (e.g., form 3926) within 15 working days of FDA's authorization of the use.

In addition to the above, FDA is continuing to work with its government partners including the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC) to develop master protocols for use by multiple investigators in order to coordinate the collection and use of COVID-19 convalescent plasma.

<sup>1</sup> Wu Z, McGoogan JM. Characteristics of and Important Lessons from the Coronavirus Disease 2019 (COVID-19) Outbreak in China: Summary of a Report of 72,314 Cases from the Chinese Center for Disease Control and Prevention. JAMA. Published online February 24, 2020. doi:10.1001/jama.2020.2648

Content current as of:  
03/24/2020

## Mr. President:

**The article of Wu Z, McGoogan JM: *Characteristics of and Important Lessons from the Coronavirus Disease 2019 (COVID-19) Outbreak in China: Summary of a Report of 72,314 from the Chinese Center for Disease Control and Prevention IS AN EPIDEMIOLOGY REPORT which NEVER SPEAKS OF THERAPY.* – The U.S. FDA, NIH, CDC, PHS, ORGANIZED, ACADEMIC, AND RESEARCH MEDICINE, etc. MISINTERPRETED this article and APPLIED IT WRONGLY!**

**-- THE TIMELY LATE ADMINISTRATION OF COVID-19 CONVALESCENT PLASMA AND the antiviral REMDESIVIR became a *de facto* faulty, tragic, DEADLY rationing METHODOLOGY late in the disease of COVID-19 DURING THE CYTOKINE CASCADE AND THE BRADYKININ STORM INSTEAD OF WITHIN <72-120 HOURS OF EARLY VIREMIA FROM THE INITIAL DOCUMENTATION by testing OF AN INDIVIDUAL'S INFECTION AND/OR INITIATION OF SYMPTOMATOLOGY. This U.S. governmental directive by edict regarding ADMINISTRATIVE TIMING OF COVID-19 Convalescent Plasma Therapy and the antiviral Remdesevir WAS ABSOLUTELY LATE and DEADLY WRONG; and it has been contributory in > 1 million deaths from COVID-19 in the U.S.A. over the last two years!**

Charles H. Andrus, M.D., F.A.C.S. 5/14/2022  
Professor, Department of Surgery, Saint Louis University School of Medicine  
Chief, Unit II General Surgery, Surgical Service (112JC), St. Louis VAMC

VA Office phone: 314-652-4100 ext. 54463  
Home phone: 314-455-9482  
Beeper: 314-491-2417



- 363) 2020-03-24 FDA: Investigational COVID-19 Convalescent Plasma – Emergency INDs. “A licensed physician must request the Emergency IND (eIND) and obtain the COVID-19 convalescent plasma from a blood center. FDA does **not** provide COVID-19 convalescent plasma for eINDs. Investigational COVID-19 Convalescent Plasma – Emergency INDs Frequently Asked Questions (/media/136470/download). [this download now points to: <https://www.fda.gov/media/136470/download> which is April 3, 2020.].
- 364) 2020-03-24 U.S. Food and Drug Administration: FDA NEWS RELEASE: Coronavirus (COVID-19) Update: Daily Roundup, March 24, 2020. <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-daily-roundup-march-24-2020>
- 365) 2020-03-24 Global Biodefense Staff: FDA allows emergency use of investigational convalescent plasma for critical COVID-19 patients. <https://globalbiodefense.com/2020/03/24/fda-allows-emergency-use-of-investigational-convalescent-plasma-for-critical-covid-19-patients/>
- 366) 2020-03-24 Desperate for Covid-19 answers, U.S. doctors turn to colleagues in China. STATnews. <https://www.statnews.com/2020/03/24/covid-19-answers-doctors-turn-to-china/>
- 367) 2020-03-24 Palca J: FDA Expedites Treatment of Serious Ill COVID-19 Patients with Experimental Plasma. NPR, March 24, 2020. <https://www.npr.org/sections/coronavirus-live-updates/2020/03/24/820939536/fda-expedites-treatment-of-seriously-ill-covid-19-patients-with-experimental-pla>
- 368) 2020-03-24 Zhang B, Liu S, Tan T, Huang W, Dong Y, Chen L, Chen Q, Zhang L, Zhong Q, Zhang X, Zou Y, Zhang S: Treatment with convalescent plasma for critically ill patients with severe acute respiratory syndrome coronavirus 2 infection. Chest 24 March 2020: e1-e5. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7195335/pdf/main.pdf>
- 369) 2020-03-24 Osborne H: What is convalescent plasma? New York health officials to start trial using blood of people recovered from coronavirus. Newsweek. 24 March 2020: 1-23. <https://www.newsweek.com/what-convalescent-plasma-new-york-health-officials-start-trial-using-blood-people-recovered-1493964>
- 370) 2020-03-25 DEPARTMENT OF HEALTH AND HUMAN SERVICES, Food and Drug Administration: **Federal Register** / Vol. 85, No. 58 / Wednesday, March 25, 2020 / Notices. 16949-16950. <https://www.govinfo.gov/content/pkg/FR-2020-03-25/pdf/2020-06222.pdf>
- 371) 2020-03-25 U.S. Food and Drug Administration: Emergency Use Authorization. Emergency Use Authorization (EUA) information, and list of all current EUAs. <https://web.archive.org/web/20200327194633/https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>

- 372) 2020-03-25 Regional Platform on Access and Innovation for Health Technologies<sup>S</sup>PR AIS , Pan American Health Organization, World Health Organization: FDA: Investigational COVID-19 Convalescent Plasma – Emergency Investigational New Drug Applications, March 25, 2020. <https://prais.paho.org/en/fda-investigational-covid-19-convalescent-plasma-emergency-investigational-new-drug-applications/>
- 373) 2020-03-26 Hopkins Tanne J: Covid-19: FDA approves use of convalescent plasma to treat critically ill patients. BMJ 2020; 368:m1256 doi: 10.1136/bmj.m1256 (Published 26 March 2020). <https://www.bmj.com/content/bmj/368/bmj.m1256.full.pdf>

**Dear Mr. President:** *I apologize for copying and pasting the following excerpted as this is copyright protected material by the BMJ Publishing Group Limited but I am presenting this to you as **Educational Material** BUT the URL to which the references point were changed by the FDA so that the eligible criteria justifying reference “1” of March 24, 2020 is extremely difficult to find: Wu Z, McGoogan JM. Characteristics of and Important Lessons from the Coronavirus Disease 2019 (COVID-19) Outbreak in China: Summary of a Report of 72,314 Cases from the Chinese Center for Disease Control and Prevention. JAMA. Published online February 24, 2020. –C. Andrus, M.D.*

Plasma from people who have recovered from covid-19 may contain antibodies to the virus that causes the disease and might be effective against the infection, the FDA said. Convalescent plasma has been studied in outbreaks of other respiratory infections, such as H1N1 influenza, SARS, and MERS. “Although promising, convalescent plasma has not been shown to be effective in every disease studied” and therefore clinical trials were needed to see if it was useful in covid-19, the FDA cautioned.

The FDA told doctors wanting to study the use of convalescent plasma to follow the usual system for an investigational new drug (IND) application.

The plasma must be collected from recovered patients who can donate blood, have had no symptoms for 14 days, and have had negative results on covid-19 tests.

However, given the current public health emergency, the FDA said it was providing emergency access to convalescent plasma for patients “with serious or immediately life threatening covid-19 infections.”

Severe disease is defined as dyspnoea, respiratory frequency  $\geq 30$  breaths per minute, blood oxygen saturation  $\leq 93\%$ , ratio of arterial partial pressure of oxygen to fraction of inspired oxygen (PaO<sub>2</sub> /FiO<sub>2</sub>) 50% within 24 to 48 hours.

Life threatening disease is defined as respiratory failure, septic shock, or multiple organ dysfunction or failure. In such cases, doctors can submit a form online or call FDA’s hotline telephone number (1-866-300-4374) to get verbal approval for treatment, which is promised within four to eight hours.

Jeffrey Henderson of Washington University School of Medicine in St Louis, Missouri, told National Public Radio, “The FDA just opened the floodgates. Our institution is scrambling to be ready to use this. There are many others, I’m sure.”<sup>3</sup>

- 1 FDA. Investigational covid-19 convalescent plasma—emergency INDs. <https://www.fda.gov/vaccines-blood-biologics/investigational-new-drug-ind-or-device-exemption-ideprocess-cber/investigational-covid-19-convalescent-plasma-emergency-ind>
- 2 Hixenbaugh M. FDA will allow doctors to treat critically ill coronavirus patients with blood from survivors. NBC News 2020 Mar 24. [www.nbcnews.com/news/us-news/fda-will-allow-doctors-treat-critically-ill-coronavirus-patients-blood-n1167831](http://www.nbcnews.com/news/us-news/fda-will-allow-doctors-treat-critically-ill-coronavirus-patients-blood-n1167831)
- 3 Palca J. FDA expedites treatment of seriously ill covid-19 patients with experimental plasma. National Public Radio, 24 Mar 2020. [www.npr.org/sections/coronavirus-liveupdates/2020/03/24/820939536/fda-expedite-treatment-of-seriously-ill-covid-19-patients-with-experimental-plasma](http://www.npr.org/sections/coronavirus-liveupdates/2020/03/24/820939536/fda-expedite-treatment-of-seriously-ill-covid-19-patients-with-experimental-plasma)

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- 374)** 2020-03-27. Hinton DM: From the EUA update 091 of July 30, 2021.  
<https://www.regeneron.com/downloads/treatment-covid19-eua-fda-letter.pdf>  
<https://www.fda.gov/media/145610/download>

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes coronavirus disease 2019 (COVID-19).<sup>1</sup> On the basis of such determination, the Secretary of HHS on March 27, 2020, declared that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3), subject to terms of any authorization issued under that section.<sup>2</sup>

- 375)** 2020-03-27 Shen C, Wang Z, Zhao F, Yang Y, Li J, Yuan J, Wang F, Li D, Yang M, Xing L, Wei J, Xiao H, Yang Y, Qu J, Qing L, Chen L, Xu Z, Peng L, Li Y, Zheng H, Chen F, Huang K, Jiang Y, Liu D, Zhang Z, Liu Y, Liu L: Treatment of 5 critically ill patients with COVID-19 with convalescent plasma. JAMA 2020 Apr 28;323 (16): 1582-1589.  
<https://jamanetwork.com/journals/jama/fullarticle/2763983>
- 376)** 2020-03-27 Roback JD, Guarner J: Convalescent plasma to treat COVID-19, Possibilities and challenges. JAMA 2020; 323(16): 1561-1562.  
<https://jamanetwork.com/journals/jama/fullarticle/2763982>
- 377)** 2020-03-28 Brunk D: FDA Oks emergency use of convalescent plasma for seriously ill COVID-19 patients. Medscape Medical News. March 28, 2020.  
<https://www.medscape.com/viewarticle/927716>
- 378)** 2020-03-29 U.S. Food and Drug Administration: Emergency Use Authorization. Emergency Use Authorization (EUA) information, and list of all current EUAs.  
<https://web.archive.org/web/20200330194732/https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>
- 379)** 2020-03-30 U.S. Department of Health & Human Services, Centers for Medicare and Medicaid Services: Center for clinical standards and quality/quality, safety and oversight group. Ref: QSO-20-15 Hospital/CAH/EMTALA REVISED.

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**Treatment:** Passive Immunization: COVID-19 Convalescent Plasma and Antibodies and Antivirals  
**Prevention:** Active Immunization: Vaccines

[https://web.archive.org/web/20200413235000if\\_/https://www.cms.gov/files/document/qso-20-15-hospital-cah-emptala-revised.pdf](https://web.archive.org/web/20200413235000if_/https://www.cms.gov/files/document/qso-20-15-hospital-cah-emptala-revised.pdf)

- 380) 2020-03-30 ACEP COVID-19 Field Guide: EMTALA Regulations and Liability.  
<https://www.acep.org/corona/covid-19-field-guide/regulations-and-liability/emptala/>
- 381) 2020-03-30 Roos D: Before vaccines, doctors ‘borrowed’ antibodies from recovered patients to save lives –Doctors first tried injecting patients with blood plasma in the early 1900s. The method has been used against diphtheria, the 1918 flu pandemic, measles and Ebola. History Channel Updated Apr 1, 2020. <https://www.history.com/news/blood-plasma-covid-19-measles-spanish-flu>
- 382) 2020-03-31 U.S. Food and Drug Administration: Emergency Use Authorization.  
<https://web.archive.org/web/20200331212526/https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>
- 383) 2020-04-01 Weise E, Johnson M: The first US coronavirus patients are being treated with convalescent plasma therapy. Will it work? Not even the doctors know. USA Today 1 Apr 2020: 1-5. <https://www.usatoday.com/story/news/health/2020/04/01/coronavirus-plasma-therapy-5-us-patients-covid-19-donors/5090946002/>
- 384) 2020-04 Chen L, Xiong J, Bao L, Shi Y: Convalescent plasma as a potential therapy for COVID-19. The Lancet 2020 April; 20: 398-400.  
[https://www.thelancet.com/pdfs/journals/laninf/PIIS1473-3099\(20\)30141-9.pdf](https://www.thelancet.com/pdfs/journals/laninf/PIIS1473-3099(20)30141-9.pdf)
- 385) 2020-04-01 O'Donnell N: BREAKING NEWS: Dr. Fauci on the fight against the virus.  
<https://www.facebook.com/CBSEveningNews/videos/norah-odonnell-should-we-be-advising-people-to-wear-masksdr-anthony-fauci-great-/204826050813336/> 2:10 – 2:48

Norah O'Donnell: With all due respect it does seem like so much of this we're making it up as we go along.

Dr. Anthony Fauci: Well, you know you make it up as you go along, Norah, because that's what you know—that's where the war is all about. I don't like to necessarily make that analogy to a war, but if you talk to the generals with experience, you have a plan. But when the bullets start flying, everything becomes a fog, and you have to play it by ear. We do have a good plan. We need to be humble that we don't know all the answers, and we don't know how exactly this is going to turn out.

Norah O'Donnell: Dr. Fauci, thank you so very much for your time and expertise.

Dr. Anthony Fauci: It's always good to be with you, Norah. Thank you.

- 386) 2020-04-02. Cerus: Cerus Corporation announces the inclusion of pathogen reduction technology in the ISBT working party recommendations for the preparation of COVID-19 convalescent plasma. BioSpace <https://www.biospace.com/article/releases/cerus->

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**Prevention:** *Active Immunization:* Vaccines

[corporation-announces-the-inclusion-of-pathogen-reduction-technology-in-the-isbt-working-party-recommendations-for-the-preparation-of-covid-19-convalescent-plasma/](#)

- 387) 2020-04-02 McCarthy A: Could plasma from recovered COVID-19 patients help others? Boston Children's Hospital. <https://answers.childrenshospital.org/covid-19-coronavirus-plasma/>
- 388) 2020-04-03. van de Veerdonk FL, Netea MG, van Deuren M, van der Meer JWM, Brüggermann RJ, van der Hoeven H: Kinins and cytokines in COVID-19: a comprehensive pathophysiological approach. Pre Prints: Posted Not PEER-reviewed. <https://www.preprints.org/manuscript/202004.0023/v1>
- 389) 2020-04-03 Langhi Junior DM, De Santis GC, Bordin JO: COVID-19 convalescent plasma transfusion. ABHH: Associação Brasileira de Hematologia, Hemoterapia e Teopla Celular 3 April 2020: 113-115. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7164882/pdf/main.pdf>
- 390) 2020-04-03 FDA: Investigational COVID-19 convalescent plasma – Emergency INDs, Frequently Asked Questions. FDA, 3 April 2020. <https://www.fda.gov/media/136470/download>
- 391) 2020-04-03 Mogensen JF: Can COVID-19 be treated? Does blood from survivors help? Experts answer our questions on antibodies. Mother Jones, 1-5. <https://www.motherjones.com/politics/2020/04/coronavirus-covid-survivors-treatments-convalescent-plasma-answers/>
- 392) 2020-04-03 Centers for Disease Control and Prevention: Interim clinical guidance for management of patients with confirmed coronavirus disease (COVID-19. (CDC recommendation started January 31, 2020 to present with last overwriting update feb 16, 2021. <http://web.archive.org/web/20200408110417/https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-guidance-management-patients.html>
- 393) 2020-04-04 Joyner M, (Principal Investigator): COVID-19 expanded access program -- Convalescent Plasma COVID-19 (coronavirus) Treatment – Mayo Clinic. First date digitally preserved by the Internet Archive (Wayback Machine). –Origin of the FDA/Mayo Clinic expanded access program. **(Compassionate Use—can't be used for Randomized Controlled Trials by definition of the NIH and FDA)** <https://web.archive.org/web/20200404010134/https://www.uscovidplasma.org/>

The protocol requires the patient or family member to consent to receiving plasma from someone who has recovered from COVID-19. Their plasma has substances that could improve chances of recovery. Only hospitalized patients referred by their health care provider will participate in this protocol.

Hospitalized patients are eligible to receive convalescent plasma if:

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**Prevention:** *Active Immunization:* Vaccines



- They are 18+ years of age
- They have laboratory-confirmed diagnosis of infection with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes COVID-19
- They are admitted to an acute care facility for the treatment of COVID-19 complications
- They have severe or life-threatening COVID-19, or judged by the treating provider to be at high risk of progression to severe or life-threatening disease
- There is informed consent provided by the patient or healthcare proxy

Severe COVID-19 is defined by one or more of the following:

- Shortness of breath (dyspnea)
- Respiratory frequency  $\geq 30/\text{min}$
- Blood oxygen saturation  $\leq 93\%$
- Partial pressure of arterial oxygen to fraction of inspired oxygen ratio  $< 300$
- Lung infiltrates  $> 50\%$  within 24 to 48 hours

Life-threatening COVID-19 is defined as one or more of the following:

- Respiratory failure
- Septic shock
- Multiple organ dysfunction or failure

Michael J. Joyner, M.D., Summary, Mayo Clinic.

<https://www.mayo.edu/research/faculty/joyner-michael-j-m-d/bio-00078027>

**394)** 2020-04-04 O'Donnell R: Before Dr. Anthony Fauci was the leading Covid-19 expert, he was captain of his high school basketball team. SBNATION

<https://www.sbnation.com/nba/2020/4/4/21207982/dr-anthony-fauci-coronavirus-covid-19-expert-high-school-basketball-team>

**395)** 2020-04-06 Xinhua: Timeline of China releasing information on COVID-19 and advancing international cooperation. ChinaDaily, 6 April 2020: 1-3.

<https://www.chinadaily.com.cn/a/202004/06/WS5e8b2f5aa31012821728496b.html>

**396)** 2020-04-06 Ledger K: Convalescent plasma: A therapy for COVID-19. Discovery's Edge—Mayo Clinic's Research Magazine 6 April 2020: 1-4.

<https://discoverysedge.mayo.edu/2020/04/06/convalescent-plasma-a-therapy-for-covid-19/>

**397)** 2020-04-06 CSL Behring: Global plasma leaders collaborate to accelerate development of potential COVID-19 hyperimmune therapy. 6 April 2020: 1-6.

<https://www.cslbehring.com/newsroom/2020/covid-19-hyperimmune> (Kennedy DB, Vice

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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*

**Prevention:** *Active Immunization:* Vaccines

President – North America Medical Affairs : A letter from CSL Behring, form-letter email 6 April 2020: 1-2).

- 398)** 2020-04-07 Bloch EM, Shoham S, Casadevall A, Sachals BS, Shaz B, Winters JL, van Buskirk C, Grossman BJ, Joyner M, Henderson JR, A, Lau B, Wesolowski A, Katz L, Shan H, Auwaerter PG, Thomas D, Sullivan DJ, Paneth N, Gehrie E, Spitalnik S, Hod EA, Pollack L, Nicholson WT, Pirofski L, Bailey JA, Tobian AAR: Deployment of convalescent plasma for the prevention and treatment of COVID-19. <https://www.jci.org/articles/view/138745>

*...Convalescent plasma has also been used in the COVID-19 pandemic; limited data from China suggest clinical benefit, including radiological resolution, reduction in viral loads, and improved survival....*

- 399)** 2020-04-07 Wu Z, McGoogan JM: Characteristics of and important lessons from the coronavirus disease 2019 (COVID-19) outbreak in China summary of a report of 72314 cases from the Chinese Center for Disease Control and Prevention. Jama April 7, 2020; 323(13): 1239-1242. <https://jamanetwork.com/journals/jama/fullarticle/2762130> (reference first released in Feb 2020, **ref. 326** above on 2020-02-24).

- 400)** 2020-04-07 Miller H: Mayo Clinic CEO says convalescent plasma could be effective treatment for coronavirus. CNBC, Apr 7, 2020. <https://www.cnbc.com/2020/04/07/mayo-clinic-ceo-says-convalescent-plasma-could-be-effective-treatment-for-coronavirus.html>

- 401)** 2020-04-07 Rivera N: Medical Task Force COVID-19 (Puerto Rico): Investigational COVID-19 Convalescent Plasma Emergency Investigational New Drug, Date April 7, 2020. <https://covid19tf.rcm.upr.edu/wp-content/uploads/sites/45/2020/04/Protocolo28-Convalescent-Plasma-1.pdf>

Since only limited data exists at this moment regarding the effectiveness of this therapy, it cannot be routinely recommended or used as a proven treatment option. The Food and Drug Administration (FDA) has provided several pathways to administer or study the use of convalescent plasma in COVID-19 patients:

- Clinical Trials: Investigators wishing to study the use of convalescent plasma need to submit a request to FDA for investigational use under the traditional IND regulatory pathway (21 CFR 312).
- Expanded Access: FDA is working with multiple federal partners and academia to open an expanded access protocol to facilitate access to COVID-19 convalescent plasma. For patients with, or at risk of, severe or life-threatening COVID-19 disease who are not eligible or who are unable to participate in randomized clinical trials, access may be available through participation of acute care facilities in an investigational expanded access protocol under an IND already in place.
- Single Patient Emergency IND: For patients who are not able to participate in a clinical trial or in an expanded access program, given the public health emergency FDA also is facilitating access to COVID-19 convalescent plasma for use in patients with serious or immediately life-threatening COVID-19 infections through the process of the patient's physician requesting a single patient emergency Investigational New Drug Application (eINDs) for the individual patient under 21 CFR 312.310. This process allows the use of an investigational drug for the treatment of an individual patient by a licensed physician upon FDA authorization. This eIND process is not for the use of COVID-19 convalescent plasma for the prevention of infection.

- 402)** 2020-04-08 Xinhua: Timeline of China releasing information on COVID-19 and advancing international cooperation. ChinaDaily 8 April 2020: 1-5. <https://global.chinadaily.com.cn/a/202004/08/WS5e8d0abaa310aeceed509be.html>

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**Treatment:** Passive Immunization: COVID-19 Convalescent Plasma and Antibodies and Antivirals  
**Prevention:** Active Immunization: Vaccines

- 403)** 2020-04-08 U.S. Food & Drug Administration: Recommendations for Investigational COVID-19 Convalescent Plasma. April 8, 2020.

<https://web.archive.org/web/20200413010215/https://www.fda.gov/vaccines-blood-biologics/investigational-new-drug-ind-or-device-exemption-ide-process-cber/recommendations-investigational-covid-19-convalescent-plasma>

### ***Patient Eligibility***

*To facilitate requests for eINDs for use of COVID-19 convalescent plasma to treat patients, health care providers seeking an emergency IND may want to consider the eligibility criteria used for the [National Expanded Access Treatment Protocol](#)[External Link Disclaimer](#). These criteria include:*

- *Laboratory confirmed COVID-19*
- *Severe or immediately life-threatening COVID-19, for example,*
  - *Severe disease is defined as one or more of the following:*
    - *shortness of breath (dyspnea),*
    - *respiratory frequency  $\geq 30/\text{min}$ ,*
    - *blood oxygen saturation  $\leq 93\%$ ,*
    - *partial pressure of arterial oxygen to fraction of inspired oxygen ratio  $< 300$ ,*
    - *lung infiltrates  $> 50\%$  within 24 to 48 hours*
  - *Life-threatening disease is defined as one or more of the following:*
    - *respiratory failure,*
    - *septic shock,*
    - *multiple organ dysfunction or failure*
- *Informed consent provided by the patient or healthcare proxy.*

- 404)** 2020-04-08 FDA: Recommendations for Investigational COVID-19 Convalescent Plasma. <https://web.archive.org/web/20200408215026/https://www.fda.gov/vaccines-blood-biologics/investigational-new-drug-ind-or-device-exemption-ide-process-cber/recommendations-investigational-covid-19-convalescent-plasma> which hyperlinked on 4/8/2020 to that which follows on 4/14/2020.

- 405)** 2020-04-08 Pharmabiz.com: Global plasma leaders collaborate to speed up development of potential COVID-19 hyperimmune therapy. Pharmabiz.com, Osaka, Japan, Wednesday, April 8, 2020. <http://www.pharmabiz.com/PrintArticle.aspx?aid=122309&sid=2>

- 406)** 2020-04-08 Spencer G: A promising COVID-19 treatment gets fast-tracked. Johns Hopkins University HUB 8 April 2020: 1-9. <https://hub.jhu.edu/2020/04/08/arturo-casadevall-blood-sera-profile/>

- 407)** 2020-04-11 Robson B: COVID-19 Coronavirus spike protein analysis for synthetic analysis for synthetic vaccines, a peptidomimetic antagonist, and therapeutic drugs, and analysis of a proposed achilles' heel conserved region to minimize probability of escape

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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and Antivirals  
**Prevention:** *Active Immunization:* Vaccines

mutations and drug resistance. Comput Biol Med 11 Apr 2020, 1-57.  
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7151553/pdf/main.pdf>

- 408) 2020-04-11 Rojas M, Rodríguez Y, Monsalve DM, Acosta-Ampudia Y, Camacho B, Gallo JE, Rojas-Villarraga A, Ramírez-Santana C, Díaz-Coronado JC, Manrique R, Mantilla RD, Shoenfeld Y, Anaya JM: Convalescent plasma in COVID-19: Possible mechanisms of action. Autoimmunity Reviews. 11 April 2020; 1-9.  
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7198427/pdf/main.pdf>

- 409) 2020-04-12 Anadolu Agency: Good response for COVID-19 plasma treatment: Red Crescent head. Hurriyet Daily News <https://www.hurriyetdailynews.com/good-response-for-covid-19-plasma-treatment-red-crescent-head-153776>

- 410) 2020-04-13 U.S. Food & Drug Administration: Recommendations for Investigational COVID-19 Convalescent Plasma. April 13, 2020.  
<https://web.archive.org/web/20200430055722/https://www.fda.gov/vaccines-blood-biologics/investigational-new-drug-ind-or-device-exemption-ide-process-cber/recommendations-investigational-covid-19-convalescent-plasma>

- 411) 2020-04-13 U.S. Food & Drug Administration: Investigational COVID-19 Convalescent Plasma – Guidance for Industry. **The original version of this directive for the Industry was issued and labelled as April 2020. The initial version of April 2020 for the Industry published for the website on which this was published can no longer be found on the Internet and the Internet Archive's first capture was April 14, 2020 of the revision version of April 13, 2020:**  
<https://web.archive.org/web/20200414181056/https://www.fda.gov/media/136798/download>

Ongoing on official FDA website URL below has been overwritten many times and captured (132 captures) by the Internet Archive from 14 Apr 2020 to 11 Mar 2022 per the Wayback Machine of the Internet Archive is: <https://www.fda.gov/media/136798/download>

As I printed out the original version of this document that is labelled **April 2020** (I assume sometime prior to April 13, 2020), I realized that original version cannot be found on the Internet. Therefore, **I have scanned and attached here my personal copy of the following to be forever recorded in history as the Original FDA version of:**

### Investigational COVID-19 Convalescent Plasma Guidance for Industry

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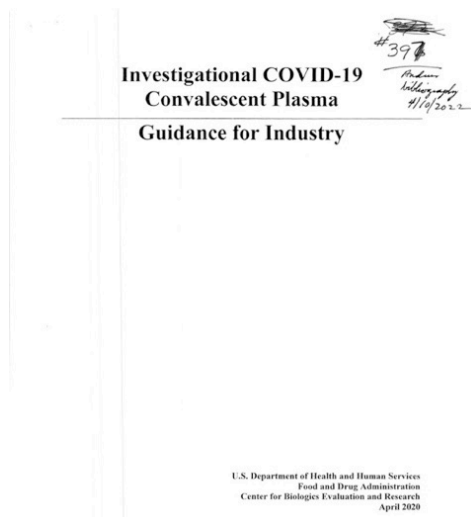
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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*  
**Prevention:** *Active Immunization:* Vaccines

U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Biologics Evaluation and Research  
April 2020

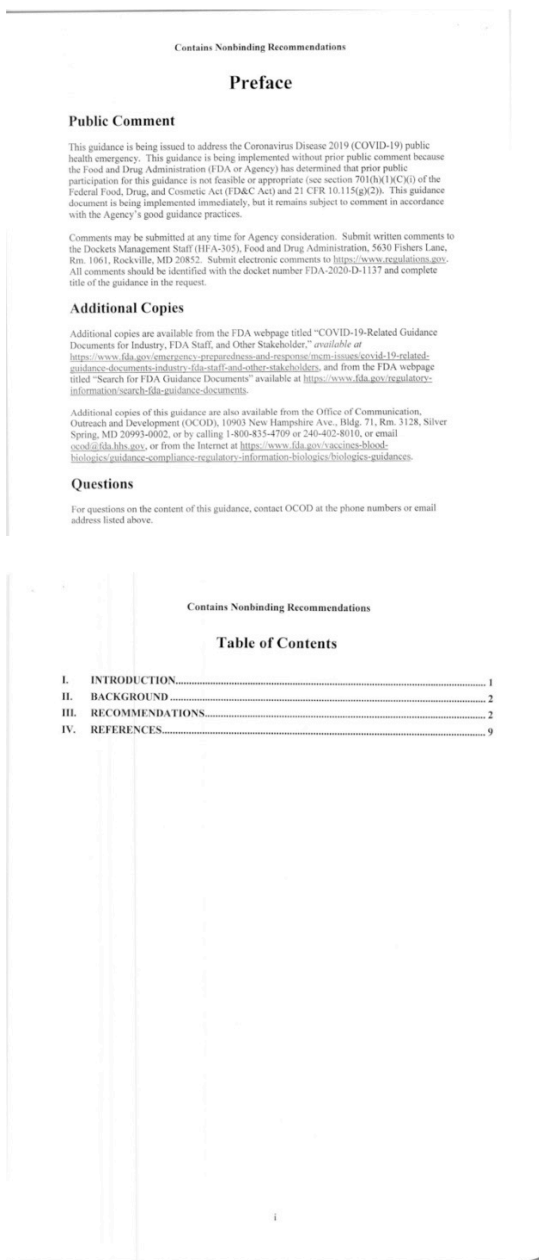
(As you will note, **the FDA already had recognized its error** of the FDA March 24, 2020, in that in its initial announcement of COVID-19 Convalescent Plasma as an Investigational drug the FDA had stipulated that COVID-19 Convalescent Plasma was **to be given only** to the very serious ill patients (late in the Cytokine Cascade and the Bradykinin Storm instead of early in the viremia) **erroneously interpreting the Chinese epidemiology journal report<sup>385</sup> regarding 72314 cases as a treatment directive (which it was not)!**). As a lie of omission which went unnoticed, the FDA removed the late recommendations of administration from all its documentations regarding COVID-19 Convalescent Plasma beginning on September 2, 2020. ***Please compare eligibility criteria for same FDA documents of*** reference 546 of September 1, 2020 versus 547 of September 2, 2020 that follow.—**THE ELIGIBILITY REQUIREMENTS FOR LATE ADMINISTRATION WERE REMOVED BY SOMEONE IN THE FDA.**



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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*  
**Prevention:** *Active Immunization:* Vaccines

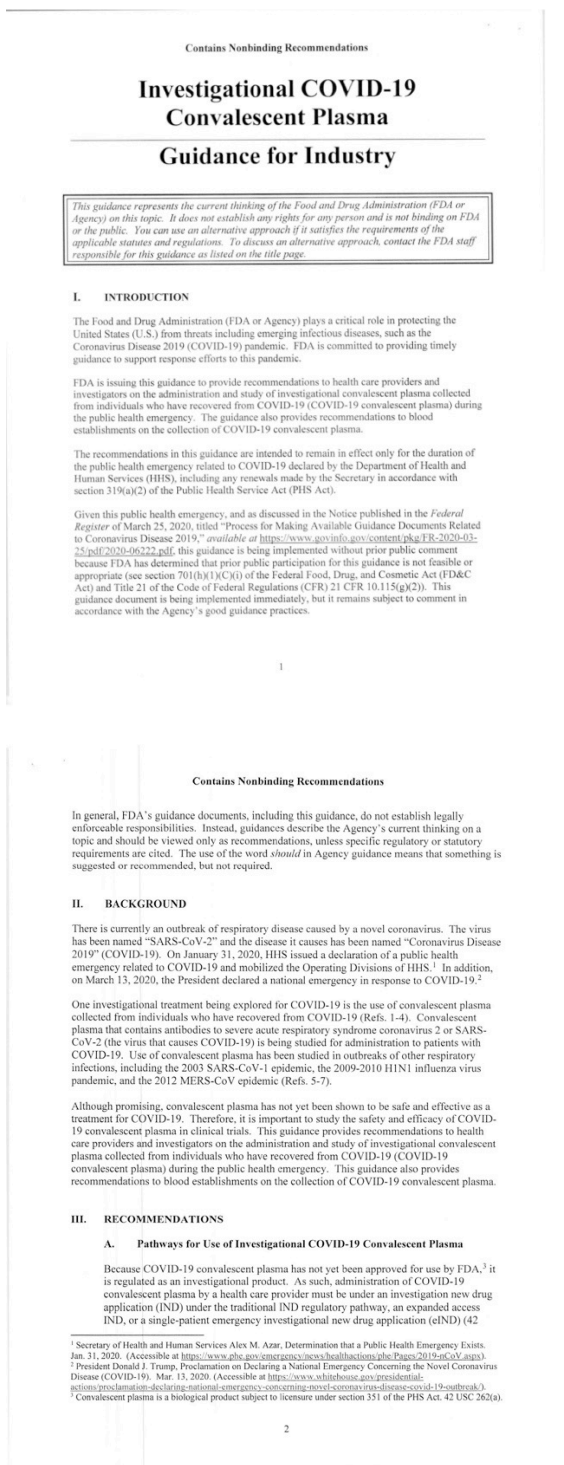




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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*  
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**Treatment: Passive Immunization:** COVID-19 Convalescent Plasma and Antibodies and *Antivirals*  
**Prevention: Active Immunization:** Vaccines

#### Contains Nonbinding Recommendations

U.S.C. 262(a)(3); 21 U.S.C. 355(j); 21 CFR 601.21; and 21 CFR 312.1). FDA does not collect COVID-19 convalescent plasma or provide COVID-19 convalescent plasma. Health care providers or acute care facilities would instead obtain COVID-19 convalescent plasma from an FDA-registered blood establishment.

The following pathways are available for administering or studying the use of COVID-19 convalescent plasma:

##### 1. Clinical Trials

Investigators wishing to study the use of convalescent plasma in a clinical trial should submit requests to FDA for investigational use under the traditional IND regulatory pathway (21 CFR Part 312). CBER's Office of Blood Research and Review is committed to engaging with sponsors and reviewing such requests expeditiously.

##### 2. Expanded Access

An IND application for expanded access is an alternative for use of COVID-19 convalescent plasma for patients with serious or immediately life-threatening COVID-19 disease who are not eligible or who are unable to participate in randomized clinical trials (21 CFR 312.305). FDA has worked with multiple federal partners and academia to open an expanded access protocol to facilitate access to COVID-19 convalescent plasma across the nation. For patients with serious or immediately life-threatening COVID-19 who are not eligible for or who are unable to participate in randomized clinical trials, access to this investigational product may be available through participation of acute care facilities in an investigational expanded access protocol under an IND that is already in place. Currently, the following protocol is in place: [National Expanded Access Treatment Protocol](#).

##### 3. Single Patient Emergency IND

Although participation in clinical trials or an expanded access program are ways for patients to obtain access to convalescent plasma, for various reasons these may not be readily available to all patients in potential need. Therefore, given the public health emergency that the COVID-19 pandemic presents, while clinical trials are being conducted and an expanded access protocol is available, FDA also is facilitating access to COVID-19 convalescent plasma for use in patients with serious or immediately life-threatening COVID-19 infections through the process of the patient's physician requesting a single patient eIND for the individual patient under 21 CFR 312.310. This process allows the use of an investigational drug for the treatment of an individual patient by a licensed physician upon FDA authorization, if the applicable regulatory criteria are met. Note, in such case, a licensed physician seeking to administer COVID-19 convalescent plasma to an individual patient must request the eIND (see 21 CFR 312.310(b)).

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#### Contains Nonbinding Recommendations

##### a. To Obtain a Single Patient Emergency IND

To obtain a single patient eIND, the provider must determine that the probable risk to the person from the investigational drug is not greater than the probable risk from the disease or condition 21 CFR 312.310(a).

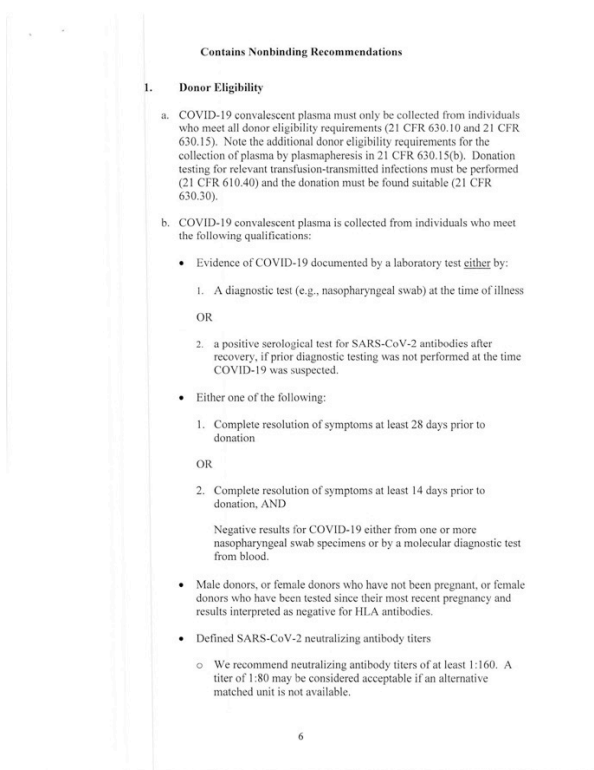
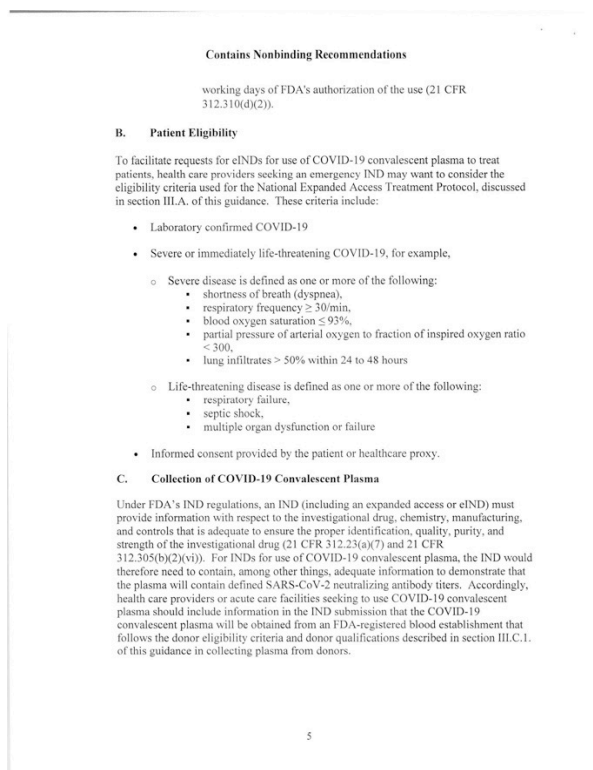
- For requests between 8am EST and 8pm EST (Mon-Sun), the requesting physician may contact FDA by completing Form FDA 3926 (<https://www.fda.gov/media/98616/download>) and submitting the form by email to [CBER\\_eIND\\_COVID-19@FDA.HHS.gov](mailto:CBER_eIND_COVID-19@FDA.HHS.gov). For eIND requests submitted via email during this time frame, FDA will respond within 4 hours.
  - The completed form should include a brief clinical history of the patient, including: diagnosis, current therapy, and rationale for requesting the proposed investigational treatment in order to meet the expanded access use requirements in 21 CFR 312.305 and 21 CFR 312.310.
  - The form should include information regarding where the COVID-19 convalescent plasma will be obtained.
  - Providers should complete the form to the extent possible, and FDA will work with the provider if additional information is required. Providers are strongly encouraged to fill out the form electronically whenever possible.
  - FDA will review the request and, upon authorization, send the requesting physician a confirmatory email that includes the emergency IND number.
- For requests between 8am EST and 8pm EST where the provider is unable to complete and submit Form 3926 due to extenuating circumstances, the provider can contact FDA's Office of Emergency Operations at 1-866-300-4374 to seek verbal authorization.
- For requests that are **overnight** between 8pm EST and 8am EST, the provider should contact FDA's Office of Emergency Operations at 1-866-300-4374 to seek verbal authorization.
  - If verbal authorization is given, the requestor must agree to submit an expanded access application (e.g., Form FDA 3926) within 15

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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*  
**Prevention:** *Active Immunization:* Vaccines



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**Treatment: Passive Immunization:** COVID-19 Convalescent Plasma and Antibodies and *Antivirals*  
**Prevention: Active Immunization:** Vaccines

**Contains Nonbinding Recommendations**

- o **NOTE:** If neutralizing antibody titers cannot be obtained in advance, consider storing a retention sample from the convalescent plasma donation for determining antibody titers at a later date.

Registered and licensed blood establishments that collect plasma intended for transfusion do not need to request a supplement to their license or obtain their own IND to collect and manufacture COVID-19 convalescent plasma for investigational use provided they 1) follow their standard operating procedures for plasma collection and all applicable regulation, and 2) collect plasma from individuals that meet the donor qualifications specified above, which would be included in the applicable IND(s) held by a health care provider or other sponsor.

Once manufactured, the COVID-19 convalescent plasma may be distributed for investigational use.

Blood establishments do not need to request an alternative procedure or exception under 21 CFR 640.120(a) to collect COVID-19 convalescent plasma.

**2. Labeling**

- a. The container label of COVID-19 convalescent plasma units must include the following statement, "Caution: New Drug--Limited by Federal (or United States) law to investigational use" (21 CFR 312.6(a)).

In addition, the requirements in 21 CFR 606.121 for the container label apply, including the requirement to include a reference to the circular of information.

- i. FDA recognizes that the current circular of information does not contain specific information about COVID-19 convalescent plasma regarding indications for use, dosage information, contraindications or cautions, but it provides information on the use of plasma.
- b. We recommend the use of a uniform container label for COVID-19 convalescent plasma. In particular, we recommend the use of the International Society of Blood Transfusion (ISBT) format specified in the United States Industry Consensus Standard for the Uniform Labeling of Blood and Blood Components Using ISBT 128.
- c. The manufacturing process used and the expiration date on the label for COVID-19 convalescent plasma should be the same as for other plasma products that are of the same type. For example, COVID-19 Convalescent Plasma, Fresh Frozen, should be frozen within 8 hours after collection.

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**Contains Nonbinding Recommendations**

stored at -18C or colder and have an expiration date one year from the date of collection.

**D. Recordkeeping**

A health care provider who is participating in an IND, including an expanded access IND or eIND, must maintain records for the COVID-19 convalescent plasma unit(s) administered to the COVID-19 patient (21 CFR 312.62). Such records should include the unique identification number(s) (e.g., the ISBT donation identification number(s)) of the unit(s).

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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*  
**Prevention:** *Active Immunization:* Vaccines



Contains Nonbinding Recommendations

IV. REFERENCES

1. Roback JD and Guarner J, Convalescent Plasma to Treat COVID-19: Possibilities and Challenges, JAMA, epub ahead of print March 27, 2020, <https://jamanetwork.com/journals/jama/fullarticle/2763982>.
2. Shen C, Wang Z, Zhao F, Yang Y, et al., Treatment of 5 Critically Ill Patients with COVID-19 With Convalescent Plasma, JAMA, epub ahead of print March 27, 2020, <https://jamanetwork.com/journals/jama/fullarticle/2763983>.
3. Chen L, Xiong J, Bao L, Shi Y, Convalescent plasma as potential therapy for COVID-19, Lancet Infect Dis, epub ahead of print February 27, 2020, [https://doi.org/10.1016/S1473-3099\(20\)30141-9](https://doi.org/10.1016/S1473-3099(20)30141-9).
4. Duan K, Liu B, Li C, Zhang H, et al., The feasibility of convalescent plasma therapy in severe COVID-19 patients: a pilot study, MedRxiv, March 23, 2020, <https://www.medrxiv.org/content/10.1101/2020.03.16.20036145v1.full.pdf>.
5. Cheng Y, Wong R, Soo YO, Wong, W, et al., 2005, Use of convalescent plasma therapy in SARS patients in Hong Kong, Eur J Clin Microbiol Infect Dis, 24(1):44-46, <https://doi.org/10.1007/s10096-004-1271-9>.
6. Leider JP, Brunker PA, Ness PM, 2010, Convalescent transfusion for pandemic influenza: preparing blood banks for a new plasma product?, TRANSFUSION, 50(6):1384-1398, <https://doi.org/10.1111/j.1537-2995.2010.02590.x>.
7. Arabi YM, Hajeer AH, Luke T, Raviprakash K, et al., 2016, Feasibility of Using Convalescent Plasma Immunotherapy for MERS-CoV Infection, Saudi Arabia, Emerg Infect Dis, 22(9):1554-1561, <https://doi.org/10.3201/eid2209.151164>.

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**412)** 2020-04-13 Gibson Dunn: FDA round-up: Overview of emergency actions to expedite the availability of medical products to combat COVID-19, April 13, 2020.  
<https://www.gibsondunn.com/wp-content/uploads/2020/04/fda-round-up-overview-of-emergency-actions-to-expedite-the-availability-of-medical-products-to-combat-covid-19.pdf>  
Pages 14 – 15.

- i. There are no FDA-approved drugs or vaccines to treat or cure COVID-19, but at the end of March, FDA launched the Coronavirus Treatment Acceleration Program (CTAP), a special emergency program to expedite the development of COVID-19 therapies. The CTAP program is using “every tool at the agency’s disposal” to provide “ultra-rapid, interactive input.”[41] FDA has turned around reviews on COVID-19 development plans within 24 hours and completed reviews of single-patient expanded-access requests within three hours. FDA has redeployed medical and regulatory staff to serve on review teams dedicated to COVID-19 therapies. FDA also has streamlined the process for developers and physicians to contact FDA with inquiries and to submit requests for the emergency use of investigational products. FDA is prioritizing these requests based on factors such as the product’s scientific merits and the stage of development. In addition to clinical studies, FDA is looking at real-world data sources to inform its evaluation of potential

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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*  
**Prevention:** *Active Immunization:* Vaccines

therapies, and FDA is leveraging scientific information being generated in China, Italy, Japan, and South Korea.

- ii. According to FDA, there are currently 10 therapeutic agents in active trials and 15 therapeutic agents in planning stages, and the Agency will publish updates as these therapies progress through the development process. Examples of potential therapies and vaccines include the following:
  1. ) Remdesivir. Remdesivir is an investigational broad-spectrum antiviral treatment, which was previously tested to treat diseases caused by other coronaviruses, such as Ebola. FDA has been working with Gilead Sciences, Inc. to expedite the clinical studies of remdesivir in adults diagnosed with COVID-19 and to permit the emergency use of the drug through an expanded access program. In March, Gilead began enrolling patients in two Phase 3, randomized, open-label, multicenter clinical studies. One of the studies will evaluate the safety and efficacy of two dosing durations in addition to the standard of care for patients with severe COVID-19. The other study will evaluate the same dosing regimens in addition to the standard of care for patients with moderate COVID-19. Other ongoing studies of remdesivir include the NIAID Phase 2 adaptive, randomized, double-blind, placebo-controlled trial and studies in China and France.
  2. ) Convalescent Plasma. Convalescent plasma, collected from individuals who have recovered from COVID-19, contains antibodies to severe acute respiratory syndrome coronavirus 2 or SARS-CoV-2 (the virus that causes COVID-19). Use of convalescent plasma as a therapeutic agent has been studied in prior outbreaks of respiratory infections, such as the H1N1 influenza pandemic. Earlier this month, FDA entered a collaboration with BARDA, the American Red Cross, and the Mayo Clinic to simplify the process for health care providers to collect, distribute, and use convalescent plasma in patients. As a result of this collaboration, FDA estimates that thousands of units of plasma will be available to patients within the coming weeks. FDA also is working with NIAID to coordinate a study of hyperimmune globulin, which is a biological product manufactured from convalescent plasma.
- iii. On April 8, 2020, FDA issued guidance on the administration and study of investigational convalescent plasma during the public health emergency.[42] Prior to this guidance, FDA had approved emergency INDs for the use of convalescent plasma in very ill COVID-19 patients. The guidance provides recommendations regarding the regulatory pathways for using investigational COVID-19 convalescent plasma, patient eligibility, the collection of COVID-19 convalescent plasma from donors, labeling, and record-keeping. In addition to the traditional IND pathway (21 C.F.R. Part 312), convalescent plasma may be permitted for investigational use through an expanded access IND for patients with serious or immediately life-threatening COVID-19 disease who are not eligible or who are unable to participate in randomized clinical trials (21 C.F.R. § 312.305) or through single patient emergency INDs following the request by a licensed physician (21 C.F.R. § 312.310). The convalescent plasma should be obtained from an FDA-registered blood establishment that follows the donor eligibility criteria and donor qualifications. Donors should have complete resolution of symptoms at least 28 days prior to donation or complete resolution of symptoms at least 14 days prior to donation and negative COVID-19 test results. FDA is relaxing requirements relating to the registration, licensure, and procedures of blood establishments that collect and distribute the convalescent plasma for investigational use.

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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*  
**Prevention:** *Active Immunization:* Vaccines

- 413) 2020-04-13 CBS Evening News with Norah O'Donnell: Racing to a Cure.  
<https://www.viacomcbspressexpress.com/cbs-news-and-stations/releases/print?id=54995>
- 414) 2020-04-14 FDA first document of Guidance for industry. [U.S. Food & Drug Administration: Investigational COVID-19 Convalescent Plasma – Guidance for Industry]  
<https://web.archive.org/web/20200414181056/https://www.fda.gov/media/136798/download>
- 415) 2020-04-14 Pardo J, Shukia AM, Chamarthi G, Gupte A: The journey of remdesivir: from Ebola and COVID-19. *Drugs in Context* 2020 Apr 14; 9: 1-9  
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7250494/pdf/dic-2020-4-14.pdf>
- 416) 2020-04-16 Komaroff AL: Reviewing Duan K *et al Proc Natl Acad Sci USA* 2020 Apr 6: Convalescent plasma therapy in patients with severe COVID-19. *NEJM Journal Watch* 16 April 2020: 5-6. <https://www.jwatch.org/na51335/2020/04/16/convalescent-plasma-therapy-patients-with-severe-covid-19>.
- 417) 2020-04-16 Cox D: The blood of coronavirus survivors could help tackle the pandemic. *Wired*, Wight Hosting, April 16, 2020. <https://www.wired.co.uk/article/coronavirus-blood-plasma-trials>
- 418) 2020-04-16. *Wired*, News Archives UK: The blood of coronavirus survivors could help cope with the pandemic. <https://www.wired.co.uk/article/coronavirus-blood-plasma-trials>  
The following was copied verbatim for documentation at the time of how China stopped there COVID-19 epidemic:
- i. *In late January, hospitals across China began using convalescent plasma as a treatment for Covid-19, and in recent weeks other countries have followed suit after the publication of initial results from Wuhan and Shanghai. While these trials involved just a small handful of patients, they received global attention as they appeared to demonstrate that convalescent plasma could aid recovery in even the most critically ill patients.*
  - ii. *“This is amazing because the vast majority of people thought that convalescent plasma could only be effective if administered early in the disease course,” says Daniele Focosi, a transfusion specialist at Pisa University Hospital in Italy. “But the Chinese case series has proved clinical benefit even at a late stage which is very intriguing because it could be a life saving treatment.”*
  - iii. *As of April 6, it was reported that 19 clinical trials of convalescent plasma are already taking place in China, the US, Italy, Iran, Mexico, and Colombia, with more planned. This week Italy is launching a nationwide initiative co-ordinated by Focosi’s team at Pisa University Hospital which will use convalescent plasma in hospitals across five more of Italy’s 20 regions, complementing an existing trial taking place in Lombardy, the epicentre of the Italian outbreak.*

- iv. *In the UK, the NHS is currently seeking donors for two trials of its own which will compare convalescent plasma against other experimental medications such as antiviral drugs. "One of these trials is to treat patients with Covid-19 pneumonia who have not reached the stage of ventilation to try to stop that happening," says David Tappin, of the University of Glasgow School of Medicine, who is looking to obtain approval to run his own trial looking at whether convalescent plasma can help protect NHS workers. "The other is to treat severely ill patients already ventilated to try to reduce time on ventilators and to reduce death."*
- v. *But finding suitable donors is not as straightforward as it might seem. While there are more than 400,000 people around the world who have recovered from Covid-19, the rapid mutation rate of the virus as it has passed between countries means that donors have to be sourced locally. As the pandemic in Italy worsened last month, China reportedly offered to ship 90 tons of convalescent plasma to Italian hospitals for emergency use, but tests soon showed that it could not be used.*
- vi. *"We have evidence that the envelope protein called the spike protein is mutating," says Focosi, who is one of the co-investigators leading the new multi-centre trial in Italy. "So convalescent plasma collected in China may not be protective for Covid-19 patients in Europe and the US. You need antibodies derived from infection to the same strain which is circulating in your area."*

**419)** 2020-04-17 Langi DM, Jr., De Santis GC, Bordin JO: Covid-19 convalescent plasma transfusion. *Hematol Transfus Cell Ther.* 2020 Apr-Jun; 42(2): 113 – 115.  
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7164882/pdf/main.pdf>

- i. ... Therefore, all therapeutic options for the potentially lethal COVID-19 infection must be discussed ethically and scientifically. Historically, convalescent plasma (CP), a passive immunotherapy, has been used as a possible therapeutic option when no proven specific vaccine or drug is available for emerging infections.<sup>1,2</sup> The administration of convalescent plasma or immunoglobulins has been shown to shorten the hospital stay and reduce the mortality rate in patients with SARS who did not respond to methylprednisolone in uncontrolled non-randomized clinical trials.<sup>3,4</sup> Cheng et al. investigated 1775 SARS patients and found that 80 patients transfused with SARS convalescent plasma had a lower mortality rate, compared to non-transfused patients (12.5% vs. 17%).<sup>4</sup>
- ii. Conclusions:
- iii. Analogous to the SARS, the COVID-19 infection progresses with an intense inflammatory response that eventually causes serious lung damage, increasing the mortality risk. In the absence of a definitive curative management, many treatment algorithms have been explored in the treatment of the COVID19. Among possible interventions, the use of plasma collected from recovered patients shows an initial promise, however published results of rigorous clinical trials are needed before we may draw definitive effectiveness conclusions on this passive antibody therapy.
- iv. The administration of the COVID-19 convalescent plasma must, however, fulfill some requirements related to availability of COVID-19 recovered donors: well-designed study protocols to guarantee the efficacy analysis of such an intervention; governmental and institutional compliance, and; laboratory support to perform serological and molecular assays, including the measurement of viral neutralization and immune response.<sup>11</sup> In addition, the connection between hospitals, blood centers and the plasma industry must follow flawless strategies, as plasma units may be frozen before distribution or be manufactured as concentrated COVID-19 immunoglobulin.

**420)** 2020-04-17 Gottlieb S: Former FDA chief Gottlieb explains the potential of Gilead's Covid-19 treatment. (The Antiviral Remdesivir)  
<https://www.cnbc.com/video/2020/04/17/gottlieb-treatment-gilead-clinical-trials-covid-19-squawk-box.html>

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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and Antivirals  
**Prevention:** *Active Immunization:* Vaccines

- 421) 2020-04-20 Cheen L, Xiong J, Bao L, Shi Y: Convalescent plasma as a potential therapy for COVID-19. [www.thelancet.com/infection](http://www.thelancet.com/infection) April 2020; 20: 398-400.  
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7128218/pdf/main.pdf>
- 422) 2020-04-22 Fleming AB, Raabe V: Current studies of convalescent plasma therapy for COVID-19 may underestimate risk of antibody-dependent enhancement. J Clinical Virology 28 April 2020; 127: 104388.  
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7187833/pdf/main.pdf> *[While ADE (antibody dependent enhancement) is theoretically possible has been reported in the treatment of Dengue fever, it has not been observed or reported in the utilization of COVID-19 Convalescent Plasma in the thousands of patients that have received CCP in the last year and a half.]*
- ...The first case series describing the use of convalescent plasma to treat critically-ill patients with COVID-19 showed clinical improvement and a decline in viral load in all treated patients , serving as a proof-on-concept for this strategy...
1. This shift may have a greater impact on disease severity if antibodies are present early in the course of infection. ...
- Current studies of convalescent plasma are limited by lack of representation of patients in the early phase of infection, as well as confounding from multiple concurrent therapies and small patient numbers. ...
- 423) 2020-04-23 Dzik S: COVID-19 Convalescent Plasma: Now is the time for better science. Transfusion Medicine Reviews 34 (2020)141-144.  
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7177063/pdf/main.pdf>
- 424) 2020-04-23 Seghatchian J, Lanza F: Convalescent plasma, an apheresis research project targeting and motivating the fully recovered COVID-19 patients: A rousing message of clinical benefit to both donors and recipients alike.  
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7177094/pdf/main.pdf>
- 425) 2020-04-24 Trump D: Donald Trump Coronavirus press conference transcript April 24. Rev Apr 24, 2020. <https://www.rev.com/blog/transcripts/donald-trump-coronavirus-press-conference-transcript-april-24> The discussion of intravenous disinfectants overshadowed the conference in which Dr. Hahn mentioned Convalescent Plasma and other anti-viral therapies. BBC: Coronavirus: Outcry after Trump suggests injecting disinfectant as treatment. 24 April 2020. <https://www.bbc.com/news/world-us-canada-52407177>
- 426) 2020-04-27 van de Veerdonk FL, Netea MC, van Deuren M, van der Meer JWM, de Mast Q, Brüggemann RJ, van der Hoeven H: Kallikrein-kinin blockade in patients with COVID 19 to prevent acute respiratory distress syndrome. eLife 2020; 9 e57555.  
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7213974/pdf/elife-57555.pdf>



- 427) 2020-04-28 Duan K, Liu B, Li C, Zhang H, Yu T, Qu J, Zhou M, Chen L, Meng S, Hu Y, Peng C, Yuan M, Huang J, Wang Z, Yu J, Gao X, Wang D, Yu X, Li L, Zhang J, Wu X, Li B, Xu Y, Chen W, Peng Y, Hu Y, Lin L, Liu X, Huang S, Zhou Z, Zhang L, Wang Y, Zhang Z, Deng K, Xia Z, Gong Q, Zhang W, Zheng X, Liu Y, Yang H, Zhou D, Yu D, Hou J, Shi Z, Chen S, Chen Z, Zhang X, Yang X: Effectiveness of convalescent plasma therapy in severe COVID-19 patients. PNAS April 28, 2020; 117 (17): 9490-9496.  
<https://www.pnas.org/content/pnas/117/17/9490.full.pdf>
- 428) 2020-04-28 Tay MZ, Poh CM, Renia L, MacAry PA, Ng LFP: The trinity of COVID-19: immunity, inflammation and intervention.  
[https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7187672/pdf/41577\\_2020\\_Article\\_311.pdf](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7187672/pdf/41577_2020_Article_311.pdf)
- 429) 2020-04-28 Zhu M, Hu K, Zhu Z: Use of convalescent plasma in COVID-19 patients in China. Transfusion Clinique et Biologique 28 April 2020: 1-2. <https://www.em-consulte.com/showarticlefile/1367091/main.pdf>
- 430) 2020-04-28 NCR Editorial Staff: Editorial: Dolan delivers the church to Trump and the GOP. National Catholic Reporter Apr 28, 2020.  
<https://www.ncronline.org/news/opinion/editorial-dolan-delivers-church-trump-and-gop>
- 431) 2020-04-29 Herper M, Feuerstein A: Critical study of Gilead's Covid-19 drug show patients are responding to treatment, NIH says. Statnews 29 Apr 2020: 1-8.  
<https://www.statnews.com/2020/04/29/gilead-says-critical-study-of-covid-19-drug-shows-patients-are-responding-to-treatment/>
- 432) 2020-04-29 Fung K: Dr. Fauci says remdesivir trial shows drug has promise as FDA plans to announce emergency use. Newsweek 29 Apr 2020: 1-10.  
<https://www.newsweek.com/dr-fauci-says-remdesivir-trial-shows-drug-has-promise-fda-plans-announce-emergency-use-1501028>
- 433) 2020-04-29 Gittleson B: Trump, Fauci tout 'good news' from remdesivir drug trial in treating COVID-19. ABCNews 29 Apr 2020. <https://abcnews.go.com/Politics/trump-fauci-tout-good-news-remdesivir-drug-trial/story?id=70407208>
- 434) 2020-04-29 Lovelace B: Dr. Anthony Fauci says Gilead's remdesivir will set a new 'standard of care' for coronavirus treatment. CNBC. <https://www.cnn.com/2020/04/29/dr-anthony-fauci-says-data-from-remdesivir-coronavirus-drug-trial-shows-quite-good-news.html>
- 435) 2020-04-29 Catanzaro M, Fagiani F, Racchi M, Corsini E, Govoni S, Lanni C: Immune response in COVID-19: Addressing a pharmacological challenge by targeting pathways triggered by SARS-Co V-2. Nature 29 May, 2020; 5:84: 1-3.  
<https://www.nature.com/articles/s41392-020-0191-1.pdf>

- 436) 2020-04-29 Xi A, Zhuo M, Dai J, Ding Y, Ma X, Ma X, Wang X, Shi L, Bai H, Zheng H, Nuernberger E, Xu J: Epidemiology and clinical characteristics of discharge infected with SARS-CoV-2 on the Qinghai Plateau. J Medical Virology May 21, 2020; 92(11): 2528-2535. <https://onlinelibrary.wiley.com/doi/epdf/10.1002/jmv.26032>

Thus, our 3 severe patients were given convalescent plasma (50 ml, qod, twice) collected from 2 patients who had recovered from COVID-19. We detected SARS-CoV-2 antibodies (IgG and IgM) from the convalescent plasma of one donated patient using chemiluminescent immunoassay. The level of IgG was very high (>30 AU/ml) and IgM (1:80) was 3,464 AU/mL. As expected, the level of IgM was very low (0.093 AU/mL). The CT images, blood gas analysis and symptoms improved the convalescent plasma transfusion. No adverse events were observed. One possible explanation for the efficacy of convalescent plasma is that the antibodies from convalescent plasma might suppress viraemia.<sup>23</sup>

- 437) 2020-05-01 C-SPAN: President Trump Oval Office Remarks on Remdesivir. 2020 May 01. <https://www.c-span.org/video/?471735-1/president-trump-oval-office-remarks-remdesivir>

Mr. O'Day, Gilead Sciences CEO: What I'd like to say is that, you know, on behalf of Gilead, to the President's point, we feel a tremendous responsibility. We're humbled by this being an important first step for patients, for hospitalized patients. We want to make sure nothing gets in the way of these patients getting the medicine. So we made a decision to donate about 1.5 million vials of remdesivir.

- 438) 2020-05-01 Sheridan C: Convalescent serum lines up as first-choice treatment for coronavirus. Nature Biotechnology 01 May 2020. <https://www.nature.com/articles/d41587-020-00011-1>

- 439) 2020-05-01 U.S. Food & Drug Administration: Investigational COVID-19 Convalescent Plasma – Guidance for Industry. <https://web.archive.org/web/20200526150255/https://www.fda.gov/media/136798/download>

- 440) 2020-05-01 Pérez-Cameo C, Marín-Lahoz J: Serosurveys and convalescent plasma in COVID-19. EclinicalMedicine 23 (2020) 100370. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7252163/pdf/main.pdf>

The current pandemic is not only overwhelming the health systems of the affected countries but also is killing thousands of other ways healthy adults. Convalescent plasma has been proposed [1] and approved to treat COVID-19 based on the experience acquired treating other viral diseases such as influenza, Ebola, and SARS [2]. It is considered a safe treatment (at least its side effects and contraindications are well known) and it has proven to be efficacious in several viral infections for more than a century. Currently, several countries and health institutions are trying to gather convalescent sera for either empirical treatment or clinical trials. Based on the WHO interim guidance developed for the 2014 Ebola outbreak [3], convalescent plasma has advantages over other proposed treatment: it requires low technology (and therefore it can be produced where required independent of pharmaceutical companies), it is low cost and its production is easily scalable as long as there are sufficient donors.

- 441) 2020-05-01 Hinton D, FDA Chief Scientist: U.S. Food & Drug Administration Emergency Use Authorization (EUA) regarding Remdesivir. Letter from RADM Hinton to Ms Rhoades, Gilead Sciences, Inc. (Initial EUA).  
<https://web.archive.org/web/20200501204823/https://www.fda.gov/media/137564/download>

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## II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited as follows:

- Distribution of the authorized remdesivir will be controlled by the United States (U.S.) Government for use consistent with the terms and conditions of this EUA. Gilead will supply remdesivir to authorized distributors<sup>4</sup>, or directly to a U.S. government agency, who will distribute to hospitals and other healthcare facilities as directed by the U.S. Government, in collaboration with state and local government authorities, as needed;
- The remdesivir covered by this authorization will be used only to treat adults and children with suspected or laboratory confirmed COVID-19 and severe disease defined as  $SpO_2 \leq 94\%$  on room air, requiring supplemental oxygen, mechanical ventilation, or extracorporeal membrane oxygenation (ECMO); ***(The mechanism of remdesivir "...acts as a nucleoside analog and inhibits RNA-dependent RNA polymerase (RdRp) of coronaviruses...").*** Kokic G, Hillen HS, Tegunov D, Dienemann C, Seitz F, Schmitzova J, Farnung L, Siewert A, Hobartner C, Cramer P: Mechanism of SARS-CoV-2 polymerase stalling by remdesivir. Nature Communications (2021)12:279 <https://doi.org/10.1038/s41467-020-20542-0>. <https://www.nature.com/articles/s41467-020-20542-0.pdf> ***Thus, the administration of remdesivir should be given early during the viral replication phase (best in <72 hours from diagnosis) rather than late in the symptomatology of COVID-19 cytokine storm and bradykinin increase.)***
- Remdesivir is administered in an in-patient hospital setting via intravenous (IV) infusion by a healthcare provider; and
- The use of remdesivir covered by this authorization should be in accordance with the dosing regimens as detailed in the authorized Facts Sheets.

- 442) 2020-05-01 FDA: Recommendations for Investigational COVID-19 | FDA 1 May 2020: 1-6. <http://web.archive.org/web/20200502165610/https://www.fda.gov/vaccines-blood-biologics/investigational-new-drug-ind-or-device-exemption-ide-process-cber/recommendations-investigational-covid-19-convalescent-plasma>

- 443) 2020-05-01 U.S. Department of Veterans Affairs, VA Pharmacy Benefits Management Services: Remdesivir emergency use authorization (EUA) Requirements, May 2020.  
[https://web.archive.org/web/20201020111539/https://www.va.gov/covidtraining/docs/20200618\\_Dynamic\\_Drugs\\_in\\_the\\_Battle\\_of\\_COVID\\_19/Remdesivir\\_Emergency\\_Use\\_Authorization\\_Requirements.pdf](https://web.archive.org/web/20201020111539/https://www.va.gov/covidtraining/docs/20200618_Dynamic_Drugs_in_the_Battle_of_COVID_19/Remdesivir_Emergency_Use_Authorization_Requirements.pdf)

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**Prevention:** Active Immunization: Vaccines

**INCLUSION CRITERIA** *(The patient must meet all these criteria. All answers must be **YES** to receive agent).*

Patient is hospitalized with laboratory confirmed COVID-19 diagnosis YES NO

The patient meets at least one of the following: need for mechanical ventilation, extracorporeal membrane oxygenation (ECMO), supplemental oxygen, or room air O<sub>2</sub> saturation  $\leq 94\%$  YES NO

Counseling provided and documented in the electronic health record as per EUA \*\* YES NO

\*\*The provider has communicated with the patient/caregiver information consistent with the “Fact Sheet for Patients and Patients/Caregivers” prior to the patient/caregiver information has been given the Fact sheet, informed that remdesivir is an unapproved drug authorized for use under EUA, given information on alternatives and their risks and benefits, and the patient/caregiver has the right to refuse or accept

- 444) 2020-05-02 Dowdy D, D’Souza G: Early herd immunity against COVID-19: A dangerous misconception. Johns Hopkins Coronavirus Resource Center.  
<https://coronavirus.jhu.edu/from-our-experts/early-herd-immunity-against-covid-19-a-dangerous-misconception>

- 445) 2020-05-02 U.S. FDA: Fact sheet for health care providers emergency use authorization (EUA) of Remdesivir. (GS-5734<sup>TM</sup>)  
<https://web.archive.org/web/20200502180648/https://www.fda.gov/media/137566/download>

The U.S. Food and Drug Administration (FDA) has issued an Emergency Use Authorization (EUA) to permit the emergency use of the unapproved product remdesivir for treatment of suspected or laboratory confirmed coronavirus disease 2019 (COVID-19) in adults and children hospitalized with severe disease. Severe disease is defined as patients with an oxygen saturation (SpO<sub>2</sub>)  $\leq 94\%$  on room air or requiring supplemental oxygen or requiring mechanical ventilation or requiring extracorporeal membrane oxygenation (ECMO).

- 446) 2020-05-02 FDA: Fact Sheet for Health Care Providers Emergency Use AuthoriU.S. Department of Veterans Affairs, Veterans Health Administration. : Remdesivir FAQ  
<https://vawww.cmopnational.va.gov/cmop/PBM/Clinical%20Guidance/FAQ%20SHEETS/Remdesivir%20FAQ%20May%202020%20.docx> No URL has been captured for this domain.

- 447) 2020-05-02 Roche JA, Roche R: A hypothesized role for dysregulated bradykinin signaling in COVID-19 respiratory complications.  
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7267506/pdf/FSB2-9999-na.pdf>

- 448) 2020-05-03 Fitzgerald M: Gilead CEO says remdesivir will be available to patients this week: ‘We’ve donated the entire supply.’ CNBC 3 May 2020: 1-7.  
<https://www.cnbc.com/2020/05/03/gilead-ceo-says-remdesivir-available-to-coronavirus-patients-this-week-weve-donated-the-entire-supply.html>

- 449) 2020-05-03 Brennan M, O’Day: Transcript: Daniel O’Day discusses coronavirus treatment on “Face the Nation,” May 3, 2020. CBS Face the Nation.

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**Treatment:** Passive Immunization: COVID-19 Convalescent Plasma and Antibodies and Antivirals  
**Prevention:** Active Immunization: Vaccines

<https://www.cbsnews.com/news/transcript-daniel-oday-discusses-coronavirus-treatment-on-face-the-nation-may-3-2020/>

MARGARET BRENNAN: Joining us now is Daniel O'Day, chairman and CEO of Gilead Sciences, that's the pharmaceutical company that makes remdesivir. Good morning to you.

GILEAD CEO DANIEL O'DAY: Good morning, MARGARET. Thank you for having me on.

MARGARET BRENNAN: So this drug shaves about four days off the recovery time of someone hospitalized with coronavirus, according to the government study. Now that your company has this emergency use authorization, how quickly will the drug get to those people who need it?

O'DAY: Well, you know, I think I speak on behalf of all of us at Gilead that we are grateful and really humbled that everything has moved so quickly. You know, it's only been three months since the first case was diagnosed in the United States to the emergency use authorization that was provided this past Friday. That's thanks to a lot of patients and caregivers that participated in our clinical trials. And we are now firmly focused on getting this medicine to the- the most urgent patients around the country here in the United States. And, MARGARET, we intend to get that to patients in the early part of this next week, beginning to work with the government, which will determine which cities are most vulnerable and- and where the patients are that need this medicine.

MARGARET BRENNAN: I think that's important. You're saying you've- you've donated some of this drug to the federal government, and you will work with the federal government to decide where the drug goes? Or is that up to the federal government to decide?

O'DAY: Right, MARGARET. So we've donated the entire supply that we have within our supply chain. And we did that because we acknowledge and recognize the human suffering, the human need here and want to make sure that nothing gets in the way of this getting to patients. And what we will do is- is provide that donation to the U.S. government and they will determine, based upon things like ICU beds, where the course of the epidemic is in the United States. They will begin shipping tens of thousands of treatment courses out early this week and be adjusting that as the epidemic shifts and evolves in different parts, in different cities here in the United States.

MARGARET BRENNAN: Okay- okay, well, we have more to talk about with you, but I have to take a quick break here. So stay with us, and stay with us, all of you as well, please. More with Daniel O'Day in a moment.

(COMMERCIAL BREAK)

MARGARET BRENNAN: I want to pick up on this, you said the- the supply of one and a half million doses of remdesivir has been donated to the government. That's enough for what, 150,000 patients or so?

O'DAY: Right, MARGARET. Just to be clear, what we've done is we've donated the entirety of our supply, which is around 1.5 million vials, and that turns into around 100,000 to 200,000 treatment courses depending on whether it's a five-day or a 10-day. And this donation will be made available to patients here in America and the United States and across the world as other regulatory decisions are taken for those countries.

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MARGARET BRENNAN: This drug is clearly going to be in demand since it's the- the first sort of promising development we've had. You were at the White House, has the Trump administration talked to you at all about using the Defense Production Act to somehow mandate that you prioritize the U.S. market over foreign markets?

O'DAY: Yeah, let me say something on the supply and the demand, because, you know, I'm so proud to work with the scientists at Gilead that, you know, that quickly moved and mobilized themselves in January, long before we knew whether the medicine would be available, to increase the supply. This is a long supply process. It used to take around 12 months, and now it takes around six months. And because of the steps we took in January, we'll have significantly more supply in the second half of this year to serve the suffering and the human needs out there. We've been working very closely with the U.S. government and with other governments around the world. In terms of the allocation question, I think we're aligned with the US government to both serve the patients here in the United States and then to be able to also make sure, as a global company based here in the United States, that we can serve other countries around the world as well. We've had very good dialogues with the government and that's going well.

MARGARET BRENNAN: So they haven't talked to you about mandating the U.S. market be prioritized or taking it for the stockpile for example. You can still export it?

O'DAY: That's correct. We have been exporting for clinical trials and for compassionate use, thousands of treatment courses. And our collaboration with the government has been such that we've been very transparent with them here in the United States. And we have a good relationship on- on future allocation.

MARGARET BRENNAN: This drug you have to get through an I.V. right now, so it works for hospitalized patients. Will you develop other mechanisms? Does this ever become a pill someone can take at home?

O'DAY: Yes. It's important to note that this medicine is really right now for the most severe patients in the hospital, and it's given by I.V. either through a five-day treatment course or a 10-day treatment course, depending on the stage and nature of the patient. But our scientists have been working since earlier this year to say, are there other ways that we could deliver this medicine, potentially as Dr. Gottlieb mentioned, to earlier patients. And in order to do that, we're looking at formulations such as subcutaneous formulations that may be given outside the hospital setting and possibly an inhaled version. This medicine is not suitable for oral administration because of the way it's metabolized. But there are ways we can look at formulations potentially that would get us to earlier patients and patients outside the hospital setting. That research is still ongoing yet, hasn't yet read out. And we'll certainly keep you up to speed on that.

MARGARET BRENNAN: All right. We will be watching. Thank you very much, Mr. O'Day.

O'DAY: Thank you.

450) 2020-05-05 Siegel E: This is how physics, not math, finally resolved Zeno's famous paradox. Forbes <https://www.forbes.com/sites/startswithabang/2020/05/05/this-is-how-physics-not-math-finally-resolves-zenos-famous-paradox/?sh=24f6f51c33f8>

451) 2020-05-05 – 2020-09-18: *Historic St. Mary's Mission & Museum est. 1841*: Fr. Pierre Jean De Smet, S.J., 1801-1873. <https://www.saintmarysmission.org/fr-desmet>

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### ***The Early Montana Missions***

Competition for land and resources spurred the Salish to seek what they believed to be the mysterious power of the white man's religion; to gain strength and power over their enemies, the Blackfeet. In the 1830's, the Flathead, Nez Perce and Iroquois tribes sent four delegations to St. Louis in search of Catholic priests, or "Blackrobes". In 1839, they asked Jesuit priest Pierre-Jean De Smet, who three years later followed them back along an ancient trail to the Bitterroot Valley of Western Montana.

The "Blackrobes" established St. Mary's Mission near present-day Stevensville. They taught the native people a belief in Christianity in addition to farming and domestic skills. It was at St. Mary's Mission that Montana's first sawmill was constructed, the first crops were cultivated, and a water-powered gristmill was first put to use.

St. Mary's closed in 1850, and the Jesuit influence expanded with the development of the St. Ignatius Mission. Father De Smet and Father Adrian Hoecken and Joseph Menetrey built several log buildings, including a chapel, two houses, a carpenter's shop and a blacksmith shop. At St. Ignatius, the priority was to establish a mission school to fulfill an educational provision in the Hellgate Treaty of 1855. —*On the wall of the one room chapel of the U.S. Department of Agriculture Museum, Missoula, MT.*

- 452) 2020-05-06 Li X, Ma X: Acute respiratory failure in COVID-19: is it "typical" ARDS? [https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7202792/pdf/13054\\_2020\\_Article\\_2911.pdf](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7202792/pdf/13054_2020_Article_2911.pdf)
- 453) 2020-05-08 Choudhury A, Mukherjee S: In silico studies on the comparative characterization of the interactions of SARS-CoV-2 spike glycoprotein with ACE-2 receptor homologs and human TLRs. JK Me Virol 2020; <https://onlinelibrary.wiley.com/doi/10.1002/jmv.25987>
- 454) 2020-05-08 World Health Organization: Commemorating Smallpox Eradication – a legacy of hope, for COVID-19 and other diseases. <https://www.who.int/news/item/08-05-2020-commemorating-smallpox-eradication-a-legacy-of-hope-for-covid-19-and-other-diseases>
- 455) 2020-05-10 Pawar AY, Hiray AP, Sonawane DD, Bhambar RS, Derle DV, Ahire YS: Convalescent plasma: A possible treatment protocol for COVID-19 patients suffering from diabetes or underlying liver diseases. Diabetes & Metabolic Syndrome: Clinical Research & Reviews 10 May 2020; 14: 665-669. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7214325/pdf/main.pdf>
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  - b. "An inoculation doctor would cut an incision in the flesh of the person being inoculated and implant a thread laced with live pustular matter into the wound," explains Fenn. "The hope and intent was for the person to come down with smallpox."

When smallpox was conveyed in that fashion, it was usually a milder case than it was when it was contracted in the natural way.”

- c. Variolization still had a case fatality rate of 5 to 10 percent. And even if all went well, inoculated patients still needed a month to recover. The procedure was not only risky for the individual patient, but for the surrounding population. An inoculee with a mild case might feel well enough to walk around town, infecting countless others with potentially more serious infections.
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U.S. Department of Health and Human Services, Food and Drug Administration, Center for Biologics Evaluation and Research: Investigational COVID-19 convalescent plasma – Guidance for Industry. April 2020, Updated May 1, 2020: 1-8.  
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...The curative effect of convalescent plasma is closely related to the quality, dose, antibody titer and infusion time of the plasma. ...

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Convalescent plasma The FDA has recently approved convalescent plasma for serious or immediately life-threatening COVID-19 infections under emergency Investigational New Drug Application (eINDs) [80]. Convalescent plasma has been previously studied during other epidemics including H1N1 influenza virus pandemic, SARS-CoV-1 epidemic, and the MERS-CoV epidemic. Recently, a preliminary case series of five intubated COVID-19 patients with ARDS showed promising results. These patients received 400 ml of convalescent plasma containing neutralizing SARS-CoV-2-specific antibody (IgG) from recovered COVID-19 donors. All patients had gradual clinical and radiological improvement within 3 days and four patients no longer required respiratory support by day 9, viral loads also became negative within 12 days after transfusion. Seven clinical trials are currently registered [7,38,81].

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To develop therapeutics to treat the 2019 novel coronavirus, the US Department of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response (ASPR) will expand an existing collaboration with US biotech Regeneron Pharmaceuticals (Nasdaq: REGN), whose shares rose 4.5% to \$372.16 on the news yesterday.

"Emerging infectious diseases can present serious threats to our nation's health security," said Rick Bright, deputy assistant secretary for preparedness and response and director of the Biomedical Advanced Research and Development Authority (BARDA) at ASPR, adding: "Working as public-private partners like we have with Regeneron since 2014, we can move rapidly to respond to new global health threats."

"The life-saving results seen with our investigational Ebola therapy last year underscore the potential impact of Regeneron's rapid response platform for addressing emerging outbreaks," said Dr George Yancopoulos, president and chief scientific officer of Regeneron. "Our unique suite of technologies expedites and improves the drug discovery and development process at every

stage, positioning Regeneron to respond quickly and effectively to new pathogens. We are eager to expand our productive collaboration with BARDA and are already working hard to address the novel coronavirus that is causing worldwide concern," he noted.

The BARDA and Regeneron now will leverage their partnership agreement to develop multiple monoclonal antibodies that, individually or in combination, could be used to treat this emerging coronavirus, also known as 2019-nCoV.

#### Will leverage Regeneron's VelocImmune platform

Medicines developed for 2019-nCoV through the expanded BARDA-Regeneron partnership will leverage Regeneron's monoclonal antibody discovery platform called VelocImmune, part of the company's VelociSuite technology.

In addition to expanded collaboration with Regeneron, BARDA is working with counterparts across the government, including within HHS and with the Department of Defense. The team is reviewing potential vaccines, treatments and diagnostics from across the public and private sectors, particularly products in development for MERS or Severe Acute Respiratory Syndrome (SARS), to identify promising candidates for development to detect, protect against or treat 2019 nCoV.

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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*  
**Prevention:** *Active Immunization:* Vaccines

*Statement 8 Convalescent plasma therapy should probably be used for severe and critically ill patients with COVID-19 (Grade 2+, weak recommendation).*

*Rationale Convalescent plasma has been testified to suppress viremia, shorten the hospital stay, and reduce mortality during several virus epidemics. ...*

*...regardless of these limitations, since there are still no specific etiological treatments for COVID-19, and convalescent plasma is available, it is reasonable to use it in the treatment of COVID-19 patients.*

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**Dr. FAUCI:** Right now we have a major push on a program to develop monoclonal antibodies, convalescent plasma, and hyperimmune globulin, all of which are founded on the same principle of using an antibody that is directed against the virus for either prophylaxis or treatment. And I think you're going to see it's going to be both. We'd like to have available for those who are at risk—elderly and those with underlying conditions—either monoclonal antibodies or convalescent plasma. That's a very, very high priority.

.

**Dr Bauchner:** Your equanimity, does it come from your parents? Does it come from your Jesuit education? It's extraordinary under the face of remarkable criticism, almost always unfair.

**Dr Fauci:** I think it does come a lot from my parents. My father was very much of a tolerant person who would accept people for what they are and very rarely ever criticized anybody. I went to a Jesuit high school in Manhattan, and from there I went to a Jesuit college. I think it was just right for me because I had always been interested in public service and not being somebody that ever attacks anybody, that accepts them for who they are and what they are. So it was kind of the perfect atmosphere to me to be educated in, and I just carried it along with me.

Feuerherd P: Dr. Fauci is dedicated to public service, formed at Jesuit high school. Catholic Review—Inspiring the Archdiocese of Baltimore. 2020 March 30. <https://catholicreview.org/dr-fauci-is-dedicated-to-public-service-formed-at-jesuit-high-school/>

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### **Convalescent plasma**

Convalescent plasma is also a potentially promising strategy to treat COVID-19. In a recent case study, the clinical status of all the five critically ill COVID-19 patients receiving convalescent plasma showed a significant improvement within 1 week following the infusion, normalization of body temperature, as well as scores of the sequential organ failure assessment. Moreover, within 1-12 days following the infusion, the neutralizing antibody titers of the patients improved and the respiratory samples tested negative for SARS-CoV-2 (ref. <sup>62</sup>). In another study of 10 severe cases, the viral titers were undetectable following the infusion in seven patients who had previously high viremia<sup>63</sup>. Previous studies on other respiratory viral diseases provided some evidences on the efficacy of convalescent plasma on treating severe and critical viral diseases. Several studies in SARS patients reported that the use of convalescent plasma was linked to reduced hospital stay and reduced mortality<sup>64,65</sup>. Clinical trials also showed that in patients with severe H1N1 influenza A, in the 2009 pandemic, therapy with convalescent plasma from patients who recovered, especially within 5 days of symptom onset, resulted in a lower viral load and lower mortality<sup>66,67</sup>. Subsequent analysis showed that the mortality of patients with severe acute viral respiratory infections was reduced after therapy with convalescent plasma, while absence of adverse events or complications were observed<sup>68</sup>.

Nevertheless, there are still issues we need to tackle. The first question is when to collect plasma from recovered COVID-19 patients. Recent work by To et al.<sup>25</sup> showed that, day 10 after symptom onset, both IgG and IgM antibodies increased in the majority of patients, while seroconversion was observed with the first 3 weeks. Importantly, the anti-SARS-CoV-2 IgG and IgM antibody levels against the internal nucleoprotein and the spike S1 domain correlated with neutralizing activity. Therefore, it would be ideally to collect convalescent plasma from week 3 after symptom onset. Despite hundreds of patients had recovered from COVID-19, eligible convalescent plasma is quite limited as the donors have to pass physical and laboratory examination, and plasma should be tested for SARS-CoV-2 nuclear acid, HIV-1, HBV, and HCV, as well as antibody titers, to list a few. The second question is deciding which patients and when should receive the convalescent plasma. The effects of convalescent plasma are difficult to observed when used in critical patients with multiple organ failure, as the viral load in this kind of population is quite high. Hence it is preferably to use convalescent plasma in mild patients whose diseases was deteriorating in their early phase of diseases. Normally, in COVID-19, the viral load peaked at the first week of illness, and then slowly decline during the subsequent week<sup>25</sup>. Accordingly, in principle, the most effective to administer the convalescent plasma is at the early phases of the disease. The biggest challenge is that it is quite difficult to identify which patient will deteriorate in the early stage. Several risk factors including older age, male, multiple comorbidities, elevated IL-6, and elevation in D-dimer levels that are associated with bad outcomes may be used as surrogate markers<sup>10</sup>. Provided further studies demonstrate its efficacy in appropriately selected patients, the next step would be the production of humanized antibody at biotechnological level.

- 489) 2020-06-10 Yigenoglu TN, Hacibekiroglu T, Berber I, Dal MS, Basturk A, Namdaroglu S, Korkmaz S, Ulas T, Dal T, Erkurt MA, Turgut B, Altuntas F: CONCISE REVIEW Convalescent plasma therapy in patients with COVID-19. J Clin Apher 2020; 35: 367-373. <https://onlinelibrary.wiley.com/doi/epdf/10.1002/jca.21806>

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2020 re NIAID Case #12276.pdf ANY Person under the Freedom of Information Act (FOIA) can request NIAID Case #12276—see reference 206 in this bibliography:

While the website above the generalities, to submit FOIA request is somewhat complicated and the following disclaimer for the NIH—National Institutes of Health in part is: ...Please submit all requests through our online portal (link below) rather than mail, fax, or courier, to ensure timely logging of your requests....

First (1): <https://www.nih.gov/institutes-nih/nih-office-director/office-communications-public-liaison/freedom-information-act-office/submitting-foia-requests>

Next (2): click on the Submit a FOIA Request:

Next (3): The following disclaimer will show up which after reading it, if one wishes to proceed, you should click on “I Accept”:

**Submit a FOIA Request**

491) 2020-06-11: Stankiewicz K: Regeneron sees ‘a lot of reason for hope’ as human testing of its coronavirus drug begins. CNBC. <https://www.cnbc.com/2020/06/11/regeneron-begins-human-testing-of-its-coronavirus-antibody-drug.html>

#### KEY POINTS

- Regeneron Pharmaceuticals announced Thursday that it’s started the first clinical trial of its experimental coronavirus antibody drug.
- The antibody cocktail is being tested in four human populations, with two groups of people receiving the drug as a treatment and two as a possible prevention.
- “I think there’s a lot of reason for hope,” Regeneron’s chief scientific officer, Dr. George Yancopoulos, said on CNBC’s “Squawk Box.”
- [Regeneron Pharmaceuticals](#) announced Thursday that it’s [started the first clinical trial](#) of its experimental coronavirus antibody drug.
- The antibody cocktail is being tested in four human populations. Two groups of people will receive the drug to test its effectiveness as a treatment for Covid-19; the other two will receive it as a possible prevention.
- “We’ll be hopefully to quickly test the safety and then start understanding the efficacy for four major different settings of this virus challenge,” Regeneron’s chief scientific officer, Dr. [George Yancopoulos](#), said on CNBC’s [“Squawk Box.”](#)

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- Yancopoulos said he thinks that, “if all goes well,” the company could have “definitive data” within a few months on the effectiveness of the antibody cocktail.
- “I think there’s a lot of reason for hope,” Yancopoulos said, noting the company’s work on Ebola. But he also stressed the unpredictable nature of science and biology, saying “there’s always reasons to be concerned and to be cautious.”
- “So we’re going to be moving forward very carefully, hand-in-hand in with the FDA, and we hope sooner rather than later we can get answers that can really make a difference,” he said.
- Regeneron is the latest company to begin trials for a potential Covid-19 therapy. [Eli Lilly](#), which began trials of its antibody drug [earlier this month](#), said a treatment could be authorized, [if all goes well](#), for use as early as September. In scientific trials so far, [Gilead Sciences](#)’s antiviral remdesivir is the only drug to [show some effectiveness](#) in treating the disease.
- There are more than 7.4 million confirmed cases of Covid-19 in the world, including over 2 million in the U.S., according to the latest [data from Johns Hopkins University](#). More than 417,100 people have died worldwide, with over a quarter of the fatalities in the U.S.
- Regeneron’s drug is being tested on four distinct types of patients, including “the sickest patients” who are hospitalized and on a ventilator or oxygen support, Yancopoulos said. It’s also being tested to see whether it can prevent high-risk people from contracting the disease, such as health-care workers.
- The drug, known as REGN-COV2, is a combination of two antibodies. Yancopoulos said Regeneron firmly believes this is the correct approach to treat Covid-19 when using antibodies.
- “Just like with conventional, old fashion antiviral drugs, giving one can have enormous benefit initially but it can lead to the selection and the arise of escaped viral mutants, which can could be very dangerous and risky,” he said. “What we showed is that in order to prevent this, you have to give these antibodies in cocktails.”

**492)** 2020-06-15 Marovich M, Mascola JR, Cohen MS: Monoclonal antibodies for prevention and treatment of COVID-19. JAMA 2020 June 15; 324: 131-132.  
<https://jamanetwork.com/journals/jama/fullarticle/2767383>

The coronavirus disease 2019 (COVID-19) pandemic has created a worldwide crisis and inspired an urgent search for prevention and treatment of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection. Attention has focused on the development of vaccines, new antiviral agents, and convalescent plasma infusions. Monoclonal antibodies have received less attention even though neutralizing antibodies are a key component of protective immunity for most viral diseases. Neutralizing monoclonal antibodies to SARS-CoV-2 have the potential for both therapeutic and prophylactic applications, and can help to guide vaccine design and development.<sup>1</sup> ....

### Conclusions

Neutralizing antibodies have an important role in the protection or recovery from many viral infections. Several monoclonal antibody products will enter clinical trials over the next few months and be assessed for their ability to limit or modify SARS-CoV-2 infection. In addition, a drug that reliably prevented progression of COVID-19 would greatly reduce the concerns and uncertainty associated with SARS-CoV-2 infection and give physicians a therapeutic tool they

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must have for their patients. Establishing the therapeutic or prophylactic efficacy of monoclonal antibodies would be a major advance in the control of the COVID-19 pandemic.

**493)** 2020-06-15 FDA: Coronavirus (COVID-19) Update: FDA revokes Emergency Use Authorization for Chloroquine and Hydroxychloroquine. <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-revokes-emergency-use-authorization-chloroquine-and>

**494)** 2020-06-18 Mahant V: "Right-to-Try" experimental drugs: an overview. J Transl Med 2020; 18: 253-263. NCBI published version: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7309195/> Pdf published version: <https://translational-medicine.biomedcentral.com/track/pdf/10.1186/s12967-020-02427-4.pdf>

In May 2018, President Donald Trump signed the "Right-to-Try" Act [5]. The legislation overcame many of the regulatory barriers, limited the risks to the sponsor while implementation of the act inherently burdened the sponsor. The "Right-to-Try" legislation is in essence a derivative of the Expanded Access Programs (EAPs). Advocates such as patients, families, friends and advocacy groups of the "Right-to-Try" legislation argue that the legislation is in line within the pre-existing framework of EAPs and that the legislation: (i) provides a "streamlined" avenue for making eligible drugs available to eligible patients with no other options; (ii) it increases patient's engagement; (iii) it is a patient's journey of self-actualization; (iv) it empowers the patient about his or her own health, well-being and quality of life; (v) it provides optimism and access to novel interventions with potential therapeutic benefits that may prolong life and improve quality of life; and (vi) the patient can be treated in the USA with valuable family time, more comfort and fewer risks than being treated overseas. The critics, on the other hand, argue: (i) there is an inherent safety risk that may potentially cause more harm to the patient or even death than the benefit because the experimental drug did not undergo rigorous testing; (ii) there is a lack of oversight by the FDA, except posting of the consolidated annual summary report; (iii) the patient in most cases has limited understanding of the informed consent due to complexity and confusion of the medical terminology used in the consent form; (iv) there are therapeutic misconceptions combined with high expectations and optimism by the patient; (v) there is potentially a considerable financial burden by the patient or the patient's family because payors currently do not provide coverage and deny hospice care; (vi) there is a potential loss of trust in the regulatory agency, the sponsor and the health care provider; and (vii) there is a liability "immunity" for the health-care provider, including the drug sponsor for potential negative outcomes of the treatment unless the medical provider and the sponsor were engaged in "gross negligence, reckless or "wilful misconduct." ...

The implications of ethics, law, regulations, government policies, constitutional rights by terminal ill patients, patient advocacy groups, including stakeholders about the pros and cons echoed through the "ecosystem" of early access to investigational drugs. Under the "Right-to-Try" legislation, the eligibility to participate include: (i) the patient must have been diagnosed with a debilitating or life-threatening disease; (ii) the patient must have failed all standard of care treatments; **(iii) the experimental or the investigational drug must have completed at least phase 1 trial;** (iv) the patient must have signed an informed consent [6]; and (vi) the pharmaceutical company must be able to provide the experimental drug to the patient. Due to the potentially negative outcome about the therapeutic efficacy combined with the safety issues, most sponsors developing medications for life-threatening diseases have had reservations about participating in expanded access or the "Right-to-Try" programs. To de-risk the potential negative outcomes and the implications combined with an opportunity to target a much larger number of patients than to a few eligible patients under the

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early access programs, the sponsors' primary goal --has been to have full FDA approval of the drug. The drug approval process, of course, is lengthy and highly risky due to potential clinical trial failures along each step of the approval process. It is an expensive process—currently, estimated to be between US\$ 1.9–2.5 billion [7, 8]. ...

#### Conclusion

The progress made on several fronts in healthcare and the concerted efforts by the stakeholders, including the integral role of agencies such as World Health Organization (WHO) and Global Health Council (GHC) over the last few decades for the treatment of diseases, patient and public engagements, the role of healthcare practitioners, the role of education, data ownership, data sharing, transparency, privacy, ethics, standardization across the multi-industries, regulations, compliance, funding of programs, payment by medical insurance companies, including global policy development and implementation currently present limited opportunities and many challenges for the “Right-to-Try” experimental drugs for the treatment of life-threatening diseases. The “Right-to-Try” experimental drug is nevertheless a major “milestone” along the journey and its full impact on treating life-threatening diseases such as cancer and infectious diseases such as COVID-19 remain to be seen. One of the biggest impacts of emergency use of experimental drugs and compassionate drugs or “repurposing” of drugs is unfolding during the current coronavirus pandemic crisis.

- 495) 2020-06-19 McEnany K: White House Press Conference, June 19, 2020.

<https://www.youtube.com/watch?v=GxX6CgI7RJ4>

...Finally, well second, to finally, we are encouraged that we continue to gather positive data on a number of therapeutics: heparin; dexamethasone or steroids as it's more commonly known; convalescent plasma; and Remdesivir have all shown promise in treating coronavirus. Preliminary findings in a large UK-based recovery trial found that when steroids were used there was a 30% reduction in death for coronavirus patients on ventilators. The FDA is reviewing this recovery trial data now. Additionally, on convalescent plasma there's more encouraging news in partnership with Mayo Clinic the Trump administration move very quickly on this therapy and it's earliest days recognizing that it showed promise. Through the FDA Mayo Clinic and the administration's work in our hand-in-hand partnership, we found that this treatment is very promising--this has shown that the administration has left no stone unturned in looking at every possible treatment at the very early stages. The lead investigator of this Mayo Clinic study, Dr. Michael Joyner, summed up his work in saying that convalescent plasma “continues to look promising” noting the “excellent news of this study which covered a diverse population of patients about 20% were African-American, nearly 35% Hispanic, 5% Asian, and 40% women. Prior experience with respiratory viruses and some data that have emerged globally suggest convalescent plasma has the potential to lessen the severity or shorten the length of the illness caused by COVID-19. The results from the Mayo underscore that promise. As you can see, the Trump administration and FDA led on identifying convalescent plasma as a therapeutic and the results are encouraging...

- 496) 2020-06-20 KPIX 5, CBS SF, BayArea: Photos: Juneteenth Protester Topple Golden Park Statues of Serra, Key, Grant. <https://sanfrancisco.cbslocal.com/2020/06/20/juneteenth-protesters-topple-golden-gate-park-statues-of-junipero-serra-francis-scott-key-u-s-grant/>

- 497) 2020-06-20 Duan K, Liu B, Li C, Zhang H, Yu T, Qu J, Zhou M, Chen L, Chen Z, Zhang X, Yang X: Reply to Kesici et al. and Zeng et al.: Blocking the virus and reducing the

inflammatory damage in COVID-19. Proceedings of the National Academy of Sciences.  
<https://www.pnas.org/content/117/23/12529>

First of all, this study was a pilot trial and the aim was to investigate the safety of CP transfusion, which was defined as the primary endpoint (3). We nevertheless also explored the possible therapeutic benefits of CP by examining its effectiveness in neutralizing the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and in ameliorating clinical symptoms and paraclinical criteria in recipients. Indeed, the adverse effect was minor, whereas a quickly improved outcome of 10 severe COVID-19 patients was observed. There are of course a number of issues to be addressed, such as the confirmation of the clinical effectiveness in a phase II controlled, randomized trial.

Second, the objective for CP transfusion in severe COVID-19 therapy is based on an in-depth understanding of disease mechanisms. The pathogenesis of this epidemic involves the interaction between viral replication of SARS-CoV-2 and human immune response (4). Particularly, in severe or critical COVID-19 cases, lung alveolar macrophages or epithelial cells could produce various proinflammatory cytokines and chemokines, which recruit monocytes and neutrophils to the infection site to clear the virus particles and infected cells, resulting in uncontrolled inflammation. The uncontrolled virus infection leads to more macrophage infiltration and a further worsening of lung injury. Therefore, the key point of CP therapy is to neutralize the virus and to interrupt the vicious cycle of excessive activation of the immune response in severe patients. In our study, 200 mL CP containing neutralized antibody above 1:640 rapidly cleared the viremia and achieved clinical improvement. Considering the accessibility of plasma donors, using CP as replacement fluid for the therapeutic plasma exchange may be not feasible.

Third, the optimal treatment time and dose of CP need to be determined by the knowledge on viral proliferative kinetics. Zhou et al. (5) reported that the median viral shedding time was 20.0 d in survival patients. Huang et al. (6) observed that the viral load gradually decreased in the respiratory tract after 7 d of illness onset but can be detected after 28 d of illness onset in two-thirds of critically ill patients. Chen et al. (7) found the serum viremia was detected in 29.4% (5/17) critically ill patients and was significantly correlated with the level of interleukin-6. Thus, monitoring the dynamic changes of interleukin-6 level, which was significantly elevated in COVID-19, may help to determine the optimal treatment time, generally within 2 wk.

Finally, the optimal time for collecting CP should be determined by the time and level of total antibody production in convalescent patients. The presence of antibodies was <40% among patients within 1 wk since onset and rapidly increased to 100.0% (antibody), 94.3% (immunoglobulin M), and 79.8% (immunoglobulin G [IgG]) since day 15 after onset (8). Also, the neutralizing antibody titer was correlated with the IgG antibodies (9). The median duration of hospitalization for COVID-19 patients was 12.0 d (10). In our study, all of the donors were recovered from the common type of COVID-19. Therefore, the collection of CP from the convalescent patients may be 3 wk after the illness onset, and routine inactivation of plasma should be performed for elimination of potential existing virus. The optimal dose of CP can be calculated based on an empirical formula: volume (liters) = weight of the recipient (kilograms) × the antibody titer of CP

**498) 2020-06-22 Hurd D, Smith C, Quintana S: Demonstrators topple statues in San Francisco's Golden Gate Park. NBC BAY AREA.**

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<https://www.nbcbayarea.com/news/local/san-francisco/demonstrators-topple-statues-in-san-franciscos-golden-gate-park/2312839/>

- 499) 2020-06-23 U.S. Department of Health and Human Services: Testimony from Anthony S. Fauci, M.D. on Oversight of the Trump Administration's Response to the COVID-19 Pandemic Before House Committee on Energy and Commerce, June 23, 2020. <https://republicans-energycommerce.house.gov/hearings/oversight-of-the-trump-administrations-response-to-the-covid-19-pandemichybrid-hearing/>
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- 503) 2020-06-28 Tapper J: Trump pushes to dismantle Obamacare during pandemic. <https://www.cnn.com/videos/politics/2020/06/28/sotu-obamacare-lawsuit.cnn>
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- 505) 2020-07-03 Duda J: As COVID-19 worsens, AZ is the first state to enact 'crisis care' standards. Arizona Mirror. <https://www.azmirror.com/2020/07/03/as-covid-19-worsens-az-is-the-first-state-to-enact-crisis-care-standards/>
- 506) 2020-07-06 Arnold C: Convalescent plasma: A COVID-19 treatment speeds to clinical trials. <https://magazine.jhsph.edu/2020/convalescent-plasma-covid-19-treatment-speeds-clinical-trials>
- 507) 2020-07-07 Garvin MR, Alvarez C, Izaak Miller J, Prates ET, Walker AM, Kirtley Amos B, Justice A, Aronow B, Jacobson D: A mechanistic model and therapeutic interventions for COVID-19 involving a RAS-mediated bradykinin storm. eLife, Jul 7, 2020; 1-16 pages. <https://elifesciences.org/articles/59177> Copied *verbatim* are from pertinent sections of this

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very important article on the pathophysiology of the inflammatory storm which is relatively (>8 days) late component of COVID-19 pathologic symptomatology versus the earlier viremic phase (0 to ~8 days).

### Abstract

Neither the disease mechanism nor treatments for COVID-19 are currently known. Here, we present a novel molecular mechanism for COVID-19 that provides therapeutic intervention points that can be addressed with existing FDA-approved pharmaceuticals. The entry point for the virus is ACE2, which is a component of the counteracting hypotensive axis of RAS. Bradykinin is a potent part of the vasopressor system that induces hypotension and vasodilation and is degraded by ACE and enhanced by the angiotensin1-9 produced by ACE2. Here, we perform a new analysis on gene expression data from cells in bronchoalveolar lavage fluid (BALF) from COVID-19 patients that were used to sequence the virus. Comparison with BALF from controls identifies a critical imbalance in RAS represented by decreased expression of ACE in combination with increases in ACE2, renin, angiotensin, key RAS receptors, kinogen and many kallikrein enzymes that activate it, and both bradykinin receptors. This very atypical pattern of the RAS is predicted to elevate bradykinin levels in multiple tissues and systems that will likely cause increases in vascular dilation, vascular permeability and hypotension. These bradykinin-driven outcomes explain many of the symptoms being observed in COVID-19.

### eLife digest

In late 2019, a new virus named SARS-CoV-2, which causes a disease in humans called COVID-19, emerged in China and quickly spread around the world. Many individuals infected with the virus develop only mild, symptoms including a cough, high temperature and loss of sense of smell; while others may develop no symptoms at all. However, some individuals develop much more severe, life-threatening symptoms affecting the lungs and other parts of the body including the heart and brain.

SARS-CoV-2 uses a human enzyme called ACE2 like a ‘Trojan Horse’ to sneak into the cells of its host. ACE2 lowers blood pressure in the human body and works against another enzyme known as ACE (which has the opposite effect). Therefore, the body has to balance the levels of ACE and ACE2 to maintain a normal blood pressure. It remains unclear whether SARS-CoV-2 affects how ACE2 and ACE work.

When COVID-19 first emerged, a team of researchers in China studied fluid and cells collected from the lungs of patients to help them identify the SARS-CoV-2 virus. Here, Garvin et al. analyzed the data collected in the previous work to investigate whether changes in how the body regulates blood pressure may contribute to the life-threatening symptoms of COVID-19.

The analyses found that SARS-CoV-2 caused the levels of ACE in the lung cells to decrease, while the levels of ACE2 increased. This in turn increased the levels of a molecule known as bradykinin in the cells (referred to as a ‘Bradykinin Storm’). Previous studies have shown that bradykinin induces pain and causes blood vessels to expand and become leaky which will lead to swelling and inflammation of the surrounding tissue. In addition, the analyses found that production of a substance called hyaluronic acid was increased and the enzymes that could degrade it greatly decreased. Hyaluronic acid can absorb more than 1,000 times its own weight in water to form a hydrogel. The Bradykinin-Storm-induced leakage of fluid into the lungs combined with the excess hyaluronic acid would likely result in a Jello-like substance that is preventing oxygen uptake and carbon dioxide release in the lungs of severely affected COVID-19 patients.

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Therefore, the findings of Garvin et al. suggest that the Bradykinin Storm may be responsible for the more severe symptoms of COVID-19.

Further experiments identified several existing medicinal drugs that have the potential to be repurposed to treat the Bradykinin Storm. A possible next step would be to carry out clinical trials to assess how effective these drugs are in treating patients with COVID-19. In addition, understanding how SARS-CoV-2 affects the body will help researchers and clinicians identify individuals who are most at risk of developing life-threatening symptoms.

## Introduction

The COVID-19 beta-coronavirus epidemic that originated in Wuhan, China in December of 2019 is now a global pandemic and is having devastating societal and economic impacts. The increasing frequency of the emergence of zoonotic viruses such as Ebola, Severe Acute Respiratory Syndrome (SARS), and Middle East Respiratory Syndrome (MERS) (among others) are of grave concern because of their high mortality rate (10%–90%). Fortunately, successful containment of those pathogens prevented global-scale deaths. In contrast, the current estimates of mortality for COVID-19 are much lower (~4%), but the virus has now infected more than nine million people and caused nearly a half a million deaths. The cause of mortality appears to be heterogeneous and although it typically targets older individuals, younger individuals are also at risk. A key to combating the pandemic is to understand the molecular basis of COVID-19 that may lead to effective treatments.

Paradoxically, an opportunity that was unavailable with SARS, MERS or Ebola has arisen because of the intense, globally distributed focus of medical and scientific professionals on COVID-19 that is providing a wealth of highly diverse information and data types. Nine bronchoalveolar lavage (BAL) samples were originally collected from patients in Wuhan China for RNA sequencing in order to determine the etiological agent for COVID-19 and resulted in the sequence of the first SARS-CoV-2 viral genome. However, the human reads from these samples were discarded 3. Here, we analyze the human RNA-seq data from these BAL samples alongside 40 controls.

## Results and Discussion

### The Renin Angiotensin System (RAS)

Although pre-existing hypertension is a reported comorbidity for COVID-19, recent reports indicate hypotension is highly associated with COVID-19 patients once in the hospital (Rentsch, 2020). The RAS is an important pathway linked to these conditions because it maintains a balance of fluid volume and pressure using several cleavage products of the peptide angiotensin (AGT) and their receptors (Arendse et al., 2019, Flores-Muñoz et al., 2011, Carey, 2017). The most well-studied peptide is angiotensin II (Ang II), which typically generates vasoconstriction and sodium retention via the AGTR1 receptor and vasodilation and natriuresis when binding to the AGTR2 receptor. The RAS also includes several other lesser known peptides that are highly important; Ang1-7 binds to the MAS1 receptor, generating anti-inflammatory and vasodilatory effects, and Ang1-9 binds to the AGTR2 receptor. Ang II is produced by the enzyme ACE whereas Ang1-7 is generated by the combination of ACE and ACE2 activity and Ang1-9 by ACE2 alone. It is important, therefore, to consider all of these components in the context of the others and not any one in isolation.

ACE2 is also the main receptor for the SARS-CoV-2 virus and is not highly expressed in normal lung tissue based on the Genotype-Tissue Expression (GTEx, [gtexportal.org](https://gtexportal.org)) six population.

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However, results from our differential gene expression analysis of RAS genes in cells taken from BAL samples from individuals presenting with severe symptoms of COVID-19 (Zhou et al., 2020) demonstrates upregulation of ACE2 (199 fold) and disruption of this system compared to controls. In the COVID-19 samples, AGT (34 fold) and the enzyme that activates it (REN, 380 fold) are increased compared to controls whereas the enzymes that produce most of the cleavage products, including ACE (−8 fold), are downregulated, which will likely result in a shift of the entire RAS to produce Ang1-9. In addition, the AGTR1 (430 fold) and AGTR2 (177 fold) receptors are upregulated in BAL COVID-19 samples.

Given the central role that the angiotensin and bradykinin (BK) peptides play in COVID-19 based on our gene expression analysis from BAL samples, we next focused on the RAS- and BK-related gene pathways in lung tissue from the GTEx population; specifically, the networks of genes that are correlated and anti-correlated with the expression of the angiotensin receptors AGTR2 and AGTR1. This subset of genes was annotated with functional information and cell type involvement which resulted in a network (Figure 1) that, as would be expected, demonstrates their extensive involvement in arterial and vascular resistance and blood flow via microvascular dilation, flow, and fluid balance. The genes on the left side of the network are extensively involved in vasoconstriction and contain, among others, ACE, AGTR1, BDKR2, Nitric Oxide Synthase-1, and −2 (NOS1 and NOS2). The right side of the network is extensively involved in decreased arteriolar resistance (vasodilation), increased vascular permeabilization, and altered fluid balance and includes, among other genes, ACE2, AGTR2, and the Vitamin D Receptor (VDR). Surprisingly, we find that both sides of the network are also clearly involved in immune system modulation.

**Figure 1**

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**Functionally annotated network of genes involved in the hypertension-hypotension axis whose expression across the GTEx population is correlated and anticorrelated with the AGTR1 and AGTR2 receptors.**

When ACE is downregulated and ACE2 and the BK pathway is upregulated in the lungs of COVID-19 patients it leads to the hypotension, vascular permeability, and the Bradykinin Storm that explains much ... [see more](#)

**The bradykinin system**

Although not as widely discussed as angiotensin, BK is another potent regulator of blood pressure and can be considered essentially an extension of the RAS (Schmaier, 2002). Briefly, similar to the angiotensin peptides, BK is produced from an inactive pre-protein kininogen (either circulating - HMWK or tissue - LWMK) through activation by the serine protease kallikrein (Figure 2A). Kallikrein is represented by a cluster of serine proteases (KLK1-KLK15) on chromosome 19 with different tissue distributions; KLKB1 (on chromosome 4) is normally expressed in the pancreas and is responsible for circulating (plasma) kallikrein. These proteases are inactivated by zinc and several are known co-receptors for viruses including influenza (Kalinska et al., 2016). KLKB1 is activated by FXII of the intrinsic coagulation pathway, which is normally kept in check by the C1-Inhibitor encoded by SERPING1 (Figure 2A). This has the vital ancillary effect of inhibiting the feedback loop of FXII activation by kallikrein (Kaplan and Ghebrehiwet, 2010).

**Figure 2**

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### **Critically disrupted RAS and Bradykinin pathways in COVID-19 BAL samples.**

(A) Significantly differentially expressed genes: red ovals indicate genes upregulated in COVID-19, blue are downregulated, colors are scaled to the log2-fold-change values for COVID-19. The overall ... [see more](#)

Similar to AGTR2 stimulation, BK induces vasodilation, natriuresis, and hypotension upon activation of the BDKRB2 receptor. BK is tightly integrated with the RAS as BK receptor signaling is augmented by Ang1-9, likely by resensitization of the BDKRB2 receptor (Chen et al., 2005; Marcic et al., 1999; Erdös et al., 2002) and also because ACE degrades and inactivates BK. Interestingly, ACE has a higher affinity for BK than it does for AGT (Cyr et al., 2001) and therefore under conditions where ACE is low, the vasopressor system is tilted toward a BK-directed hypotensive axis (Figure 2A). In addition to its role in pressure and fluid homeostasis, BK is a normal part of the inflammatory response after injury and acts to induce pain via stimulation of the BDKRB1 receptor by BK1-8 (Jacox et al., 2014), which also causes neutrophil recruitment and increases in **vascular permeability** (Stuardo et al., 2004; Araújo et al., 2001; Hofman et al., 2016; Figure 2B). BK1-8 is produced by the enzyme carboxypeptidase N (CPN1 671 fold) acting on BK.

As with the RAS, the BK system is also severely affected in the COVID-19 BAL samples. The expression of the BK precursor kininogen and nearly all of the kallikreins are undetected in controls but expressed in COVID-19 BAL (Figure 2A). Most of the enzymes that degrade BK, including ACE, are downregulated (–8 fold) in COVID-19 BAL compared to controls, directing BK1-9 and BK1-8 to the upregulated receptors BKB2R (207 fold) and BKB1R (2945 fold), respectively. Of note, the pain-receptor BKB1R is normally tightly controlled and expressed only at very low levels in nearly all tissues in GTEx, but in the case of COVID-19 BAL, both BK receptors are expressed whereas they are virtually undetected in controls. Finally, F12 is unchanged but the SERPING1 (–33 fold) gene that encodes the C1-Inhibitor that inhibits FXII is highly down-regulated, which would result in even further increases in BK in COVID-19 patients given its role in KLKB1 activation (Schmaier, 2016). As described below, the resulting Bradykinin Storm is likely responsible for most of the observed COVID-19 symptoms.

### **Hyaluronic Acid synthesis and degradation**

Hyaluronic acid (HA) is a polysaccharide found in most connective tissues. HA can trap roughly 1000 times its weight in water (Cowman and Matsuoka, 2005) and when bound to water the resulting hydrogel obtains a stiff viscous quality similar to ‘Jello’ (Necas et al., 2008). HAS1, HAS2 and HAS3 are genes that encode hyaluronan synthases which are integral membrane proteins responsible for HA production (Necas et al., 2008). HA is degraded by hyaluronidases encoded by HYAL1 and HYAL2. Proteins encoded by other genes in this family (HYAL3 and HYAL4) do not appear to have a hyaluronidase activity (Harada and Takahashi, 2007; Kaneiwa et al., 2010). HYAL1 encodes a lysosomal hyaluronidase (Hyal-1) active at low pH and is responsible for intracellular degradation of HA (Harada and Takahashi, 2007). HYAL2 encodes a membrane-bound hyaluronidase (Hyal-2) responsible for extracellular degradation of HA (Harada and Takahashi, 2007). Both Hyal-1 and Hyal-2 are dependent on CD44 (an HA receptor) for activity (Harada and Takahashi, 2007).

As with the RAS and BK systems, the genes encoding HA synthesis and degradation are also severely affected in the COVID-19 BAL samples. There is significant upregulation of the genes involved in HA synthesis: HAS1 (9113 fold), HAS2 (493 fold), and HAS3 (32 fold). The CD44 gene that encodes the HA receptor required for HA degradation and the gene encoding extracellular hyaluronidase HYAL2 are both downregulated (–11 and –5 fold respectively) in the

BAL fluid of COVID-19 patients. HYAL1 is not expressed in the BAL fluid of controls or the COVID-19 patients. The result of these shifts in expression would be likely to cause an increase in the amount of HA in the bronchoalveolar space of the lungs which, combined with the vascular hyperpermeability caused by BK, could form a viscous hydrogel that would negatively impact gas exchange (Figure 3). In fact, HA in BAL fluid has previously been associated with acute respiratory distress syndrome (ARDS) where there was a significant anticorrelation between the concentration of HA and the pulmonary oxygenation index (Modig and Hällgren, 1989; Hällgren et al., 1989). HA has also been associated with pulmonary thrombosis and/or ground glass opacities in radiological findings (Bhagat et al., 2012; Han et al., 2019; Jang et al., 2014).

**Figure 3**

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**The upregulation of hyaluronan synthases and downregulation of hyaluronidases combined with the BK-induced hyperpermeability of the lung microvasculature leads to the formation of a HA-hydrogel that inhibits gas exchange in the alveoli of COVID-19 patients.**

Although not the focus of the present study, coagulopathy is commonly reported in cases of COVID-19 (The Lancet Haematology, 2020), and there are suggestions in the literature of links between RAS and coagulopathy. The Ang1-9 peptide that is increased in COVID-19 BAL stimulates thrombosis by inhibiting fibrinolysis (Mogielnicki et al., 2014). In addition to BK, ACE also degrades the antifibrotic peptide N-acetyl-seryl-aspartyl-lysyl-proline (AcSDKP), which is produced from thymosin beta-4 (TMSB4X, -130 fold) (Kanasaki, 2020). Increased fibrinolysis could therefore be achieved by increasing ACE, or by administering thymosin beta-4, which is currently in clinical trials for the treatment of cardiovascular disorders (Timbetasin). If TMSB4X is, in fact, protective, it could explain the lower incidence of COVID-19 induced mortality in women (Jin et al., 2020) because it is found on the X chromosome and escapes X-inactivation. Women therefore would have twice the levels of this protein than men, which is supported by our BAL analysis (-207 fold in males, -131 fold in females).

In addition, both the RAS and BK pathways have previously been tied to HA. It was found that Angiotensin II increased CD44 expression and hyaluronidase activity (Bai et al., 2016). As discussed above, COVID-19 likely significantly downregulates the production of Angiotensin II which is consistent with the decrease in CD44 expression that is seen in the BAL fluid of SARS-CoV-2 infected patients. Furthermore, IL2 was recently reported to be highly upregulated in symptomatic but not asymptomatic COVID-19 patients (Long et al., 2020; Paegelow et al., 1995; Mustafa et al., 2002) and is upregulated (21 fold) in the BAL samples compared to controls. This cytokine is induced by BK in the lung, and causes vascular leakage syndrome (VLS), which appears to be mediated through CD44. Interestingly, CD44 knockout mice displayed reduced IL2-induced VLS, suggesting this may be a valuable target for COVID-19 intervention.

### **Clinical description of COVID-19**

According to the CDC, the majority of SARS-CoV-2 infections are asymptomatic or mild. Those that proceed to more severe forms present with fever, a non-productive cough that may result in hemoptysis and shortness of breath. Other common symptoms are myalgia, fatigue, sore throat, nausea, vomiting, diarrhea, conjunctivitis, anorexia, and headache (cdc.gov/coronavirus/2019-ncov/hcp/clinical-guidance-management-patients.html). Reports from blood studies include leukopenia, eosinopenia, neutrophilia, elevated liver enzymes, C-reactive protein, and ferritin (Fan et al., 2020; Huang et al., 2020; Goyal et al., 2020). Furthermore, autopsies have reported extensive hyaline membrane formation in the lungs of COVID-19 patients (Barton et al., 2020; Xu



et al., 2020; Adachi et al., 2020; Mong et al., 2020). Specifically, histological analysis of the lungs of a deceased COVID-19 patient showed organizing hyaline membranes in the early stages of alveolar lesions and prominent hyaline membranes in the exudative phase of diffuse alveolar damage (Adachi et al., 2020). In a separate post mortem study of lung tissue from COVID-19 patients, microscopic examination found ‘numerous hyaline membranes without evidence of interstitial organization’ (Barton et al., 2020). Furthermore, in another autopsy study of a COVID-19 patient, histological analysis found extensive hyaline membranes, which the authors interpreted as indicative of ARDS (Xu et al., 2020). Finally, a meta-analysis showed that there was a statistically significant 4.6 fold difference in lung weight of COVID-19 patients versus controls, which they conclude is consistent with the HA-hydrogel formation known to occur in ARDS (Mong et al., 2020).

Although much focus has been on the lung due to the need for ventilator support of end-stage disease, COVID-19 also affects the intestine, liver, kidney, heart, brain, and eyes (Wadman, 2020). Nearly one-fifth of hospitalized patients experience cardiac injury (Shi et al., 2020), many of whom have had no history of cardiovascular problems prior to infection. Responses include acute myocardial injury, myocarditis, and arrhythmias (Driggin et al., 2020) that may be due to viral infection directly, which is consistent with high expression of the SARS-CoV-2 receptor ACE2 in cardiac tissue (gtexporta.org). An important extension of the RAS in controlling cardiac contraction and blood pressure is the potent inotrope apelin (APLN), which acts as an NO-dependent vasodilator when its receptor (APLNR) heterodimerizes with BDKRB1 (Bai et al., 2014). APLN (98 fold), APLNR (3190 fold) and BDKRB1 (2945 fold) are all upregulated in COVID-19 BAL. As with BK and ANG derived peptides, APLN is inactivated by Neprilysin (MME), which is significantly downregulated in the BAL samples from COVID-19 individuals (–16 fold). Therefore, increased APLN-signaling can be added to the imbalanced RAS.

In addition to cardiac dysfunction, neurological involvement in COVID-19 was revealed after an MRI assessment of COVID-19-positive patients with encephalopathy symptoms in France identified enhancement in leptomeningeal spaces and bilateral frontotemporal hypoperfusion (Helms et al., 2020) which are consistent with increased vascular permeabilization in the brain. Furthermore, earlier reports from China indicate high frequencies of dizziness, headache, as well as taste and smell impairment (Mao et al., 2020). The most recent reports from the United States and China indicate that 30–50% of COVID-19 patients experience adverse gastrointestinal symptoms (Cholankeril, 2020; Pan et al., 2020). Direct infection by the virus and damage to the kidney was also observed, specifically in the proximal tubules (Su et al., 2020). These latter two findings are not surprising given the higher expression of ACE2 in these tissues compared to tissues overall (gtexportal.org), which would facilitate infection by the virus. Finally, COVID-19 patients also frequently display skin rashes including ‘covid-toe’ that appear to be related to dysfunction of the underlying vasculature.

### **Bradykinin Storms: A model of SARS-CoV-2, COVID-19, and BK-driven Vascular Permeabilization**

Based on previous work in SARS-CoV-1 and SARS-CoV-2, it is likely that this new coronavirus enters host cells in nasal passages where the receptor ACE2 is moderately expressed. Migration to throat tissues and passage through the stomach is then possible given that SARS-CoV-2 can survive the extreme pH of the gastric tissues (Chin et al., 2020) and infection could then expand into the intestines where ACE2 levels are high (GTEx Consortium, 2013). Initial infection might not occur in the lung epithelium given that ACE2 is undetectable or expressed at extremely low levels there (GTEx Consortium, 2013). Following infection, the single polypeptide that is translated from the virus’ positive-strand RNA genome is cleaved into active proteins by the non-structural protein 3CLpro protease. This protein is then repurposed by the virus to inactivate the

host cells' first line of defense, interferon, most likely by degrading the NFkappaB activating factor IKK-gamma as has been shown to happen in the porcine coronavirus PEDV (Wang et al., 2016).

Aside from self-protection, the suppression of NFkappaB (–9 fold reduced in BAL samples) directly affects the RAS as NFkappaB normally induces the expression of ACE by binding to its promoter and increasing transcription (Garcia et al., 2016; Figure 2A). This likely relates to the role of ACE in the innate immune response that is independent of its actions on the vascular system (Bernstein et al., 2018). The virus therefore acts pharmacologically as an ACE inhibitor by reducing its RNA expression more than 10-fold, which is supported by our BAL RNA-seq analysis. Additionally, ACE2 expression is normally downregulated in-part by Ang II (Patel et al., 2016). As Ang II is the catalytic product of ACE, it would seem that the virus's ability to decrease ACE expression would have the effect of upregulating ACE2 (199 fold in our BAL analysis). In some patients, severe pulmonary involvement could occur when the virus is introduced into the intestinal lymph vessels and moves up the lymphatic system (Chen, 2020), enters the bloodstream at the thoracic duct and moves through the heart and into the lung microvasculature where it could attack cells in the lungs that now express ACE2 due to virus-induced upregulation.

Given that the high levels of ACE in the vascular bed of the lung are the major producer for circulating angiotensin-derived peptides (Studdy et al., 1983), establishment of SARS-CoV-2 in the lung will have profound effects. Downregulation of ACE here (confirmed in BAL samples from COVID-19 patients) will result in the diversion of the RAS to produce the BK-augmenting peptide Ang1-9, exacerbating BK-effects, such as pain sensitization and increased vascular permeability on a system-wide level. Expansion of this imbalance as described above (Figure 2), increases levels of BK and will result in increased vascular permeability in tissues that have been infected by SARS-CoV-2 and be most severe in those that are normally regulated by ACE. ACE may also provide a key diagnostic point as half of the variation amongst individuals can be explained by an insertion/deletion polymorphism of the gene (Rigat et al., 1990).

As mentioned above, the combination of vascular permeability and HA build up in the lungs could produce a hydrogel that significantly inhibits gas exchange in bronchoalveolar spaces. This is consistent with the autopsy reports of hyaline membranes in the lungs of deceased COVID-19 patients as well as other acute respiratory distress conditions (e.g., SARS, MERS, ARDS) (Barton et al., 2020; Xu et al., 2020; Adachi et al., 2020) Although this likely represents a late-stage event in severe cases of COVID-19, if the cause is overproduction of HA as a result of disruption of the RAS, it is also a potentially valuable intervention point because the condition is easily identified, and treatment could have rapid and significant beneficial effects.

In addition, increased levels of the vasodilating peptide APLN that are produced in COVID-19 patients could have spillover effects on cardiac function. APLN upregulates the expression of ACE2 (Sato et al., 2013) and directly affects cardiac contraction and vasodilation. Increased levels of APLN are known to be associated with cardiac arrhythmia (Salska et al., 2018) and in the case of hyper-stimulated BK output, could be causing cardiac events in COVID-19 patients. In addition, increased levels of APLN could lead to more ACE2 receptors for SARS-CoV-2 in the heart and thus stimulate further infection.

Furthermore, excess BK can lead to hypokalemia (Zhang et al., 2018), which is associated with arrhythmia and sudden cardiac death (Kjeldsen, 2010), (Bielecka-Dabrowa et al., 2012; Skogestad and Aronsen, 2018), both of which have been reported in COVID-19 patients (Huang et al., 2020; Guo et al., 2020), (Wang et al., 2020); a recent report confirms that hypokalemia is

occurring in severe cases of COVID-19 (Lippi et al., 2020). It is also notable that many of the other symptoms being reported for COVID-19 (myalgia, fatigue, nausea, vomiting, diarrhea, anorexia, headaches, decreased cognitive function) are remarkably similar to other hyper-BK-conditions that lead to vascular hyper-permeabilization such as angioedema as was recently noted (van de Veerdonk et al., 2020). In agreement with that report, our results indicate that the pathology of COVID-19 is likely the result of Bradykinin Storms rather than cytokine storms (although given the induction of IL2 by BK, the two may be intricately linked). This model predicted that a loss of ACE2 would exacerbate the BK-induced pathogenesis (van de Veerdonk et al., 2020). However, the BAL fluid expression data indicate that the Bradykinin Storm is instead caused by upregulation of ACE2 and reduced degradation of BK by ACE. Based on this data-driven model, an individual's symptomatology is likely directly related to the specific tissue distribution of viral infection around the body (Figure 4) and should be viewed in the context of an overactive bradykinin response. The majority of circulating BK is degraded in the lungs by ACE and therefore heterogeneous symptoms of COVID-19 could also be the result of systemic effects of increased levels of circulating bradykinin and the eight-fold reduction of ACE in the lung microvasculature that would normally degrade it.

**Figure 4**

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#### **Systemic-level effects of critically imbalanced RAS and BK pathways.**

The gene expression patterns from COVID BAL samples reveal a RAS that is skewed toward low levels of ACE that result in higher levels of Ang1-9 and BK. High levels of ACE normally present in the ... [see more](#)

Given this model, factors that affect RAS balance should be further investigated in the framework of diagnosis and treatment. For example, another well-documented regulator of RAS is Vitamin D (Vaidya and Williams, 2012) as the liganded Vitamin D receptor (VDR) suppresses REN expression. Patients who are deficient in Vitamin D are at-risk for ARDS in general (Dancer et al., 2015) and Vitamin D deficiencies have recently been associated with severity of illness in COVID-19 patients (Alipio, 2020). Our BAL gene expression analysis shows that VDR is 2-fold down-regulated and enzymes [CYP24A1 (465 fold), CYP3A4 (208 fold)] that catabolize Vitamin D (1,25(OH)<sub>2</sub>D) and its precursor (25OHD) (Bikle, 2014) are up-regulated in COVID-19 patients compared to controls, which will likely result in further increases in REN. Furthermore, our analysis of ChipSeq experiments from a VDR study Tuoresmäki et al., 2014 have determined that, in addition to REN, the following genes in the RAS-Bradykinin system have a VDR binding site within 20 kilobases: BDKRB1, BDKRB2, CYP24A1, DPP4, IKBKG (regulates NFκB), KLK1, KLK2, KLK4, KLK6, KLK7, KLK9, KLK10, and MME. Six of these binding sites can be tied to the following genes via chromatin structure with the use of H-MAGMA and Hi-C data (see Materials and methods): DPP4, BDKRB2, KLK6, KLK7, KLK10, and IKBKG. VDR binds to many sites in the genome with tissue-specific binding patterns so these putative associations to other genes in the RAS and BK pathways will require further investigation.

#### **Potential interventions**

Several interventional points (most of them already FDA-approved pharmaceuticals) could be explored with the goal of increasing ACE, decreasing BK, or blocking BK2 receptors (Table 1). Icatibant is a BKB2R antagonist (Dubois and Cohen, 2010) whereas Ecallantide acts to inhibit KLKB1, reducing levels of BK production (Farkas and Varga, 2011). Androgens (danazol and stanosolol) increase SERPING1, although the side effects likely make these undesirable (Wilkerson, 2012), but recombinant forms of SERPING1 (Berinert/Cinryze/Haegarda) could be administered to reduce BK levels. It should be noted that any intervention may need to be timed

correctly given that REN levels rise on a diurnal cycle (Gordon et al., 1966), peaking at 4AM which corresponds with the commonly reported worsening of COVID-19 symptoms at night. Another approach would be the modulation of REN levels via Vitamin D supplementation when warranted. 4-methylumbelliferone (Hymecromone) is a potent inhibitor of HAS1, HAS2, and HAS3 gene expression and results in the suppression of the production of hyaluronan in an ARDS model (McKallip et al., 2003; McKallip et al., 2013). Hymecromone (4-methylumbelliferone) is approved for use in Asia and Europe for the treatment of biliary spasm. However, it can cause diarrhea with subsequent hypokalemia, so considerable caution should be used if this were to be tried with COVID-19 patients (NCATS Inxight, 2020). As mentioned above, Timbetasin may reduce COVID-19 related coagulopathies by increasing fibrinolysis.

**Table 1**

**Potential therapeutic interventions, their targets, and predicted effect.**

Drug	Target	Predicted Effect
Danazol, Stanozolol	SERPING1	Reduce Bradykinin production
Icatibant	BKB2R	Reduce Bradykinin signaling
Ecaltantide	KLKB1	Reduce Bradykinin production
Beriner, Cinryze, Haegarda	SERPING1	Reduce Bradykinin production
Vitamin D	REN	Reduce Renin production
Hymecromone	HAS1, HAS2, HAS3	Reduce hyaluronan
Timbetasin	TMSB4X	Increase fibrinolysis

The testing of any of these pharmaceutical interventions should be done in well-designed clinical trials. Given the likely future outbreaks of zoonotic viruses with a similar outcome, it would be in the best interest long-term to invest in the development of small molecules that can inhibit the virus from replicating or suppressing the host immune system such as a 3CLpro inhibitor. However, to date, no large multi-centered, randomized, placebo controlled, blinded clinical trials have been done with 3CLpro inhibitors (Sisay, 2020). In the meantime, our analyses suggest that prevention and treatment centered on vascular hyper-permeability and the suppression of hyaluronan may prove beneficial in fighting the pathogenesis of COVID-19. Given the fact that two recent studies have validated our model's predictions of hypokalemia (Lippi et al., 2020) and Vitamin D deficiency (Alipio, 2020) in COVID-19 patients, we suggest that rapid testing of the pharmaceutical interventions discussed above is warranted.

## Decision letter

- **Frank L van de Veerdonk** Reviewing Editor; Radboud University Medical Center, Netherlands
- 
- **Jos WM van der Meer** Senior Editor; Radboud University Medical Centre, Netherlands
- 
- **Frank L van de Veerdonk** Reviewer; Radboud University Medical Center, Netherlands
- 
- **Roger Little** Reviewer

----- September 18, 2023 -----

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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*  
**Prevention:** *Active Immunization:* Vaccines

*In the interests of transparency, eLife publishes the most substantive revision requests and the accompanying author responses.*

### Acceptance summary:

The manuscript has highlighted a core response in COVID-19 with RAS and bradykinin which is really a different signature than any other viral pneumonia other than coronavirus infection. This supports the importance of these pathways in coronavirus and contributes to a better understanding of COVID-19. The novelty and importance is also the site of infection (the lungs) that has been studied for this signature which really adds novelty to the existing literature.

### Decision letter after peer review:

Thank you for submitting your article "A Mechanistic Model and Therapeutic Interventions for COVID-19 Involving a RAS-Mediated Bradykinin Storm" for consideration by *eLife*. Your article has been reviewed by three peer reviewers, including Frank L van de Veerdonk as the Reviewing Editor and Reviewer #1, and the evaluation has been overseen by Jos van der Meer as the Senior Editor. The following individual involved in review of your submission has agreed to reveal their identity: Roger Little (Reviewer #3).

The reviewers have discussed the reviews with one another and the Reviewing Editor has drafted this decision to help you prepare a revised submission.

We would like to draw your attention to changes in our revision policy that we have made in response to COVID-19 (<https://elifesciences.org/articles/57162>). Specifically, we are asking editors to accept without delay manuscripts, like yours, that they judge can stand as *eLife* papers without additional data, even if they feel that they would make the manuscript stronger. Thus the revisions requested below only address clarity and presentation.

### Summary:

The authors have used a systems biology approach and analyzed data from BAL (9 COVID patients) with 40 control BALs. They clearly demonstrate a signature of a dysregulated RAAS and KKS. Further analysis shows the signature is skewed towards an incapacity to dampen the KKS and bradykinin production that might lead to a bradykinin storm that could contribute to the endothelial dysfunction that results in vascular leakage seen in the early stages of patients admitted to the hospital with COVID. The data are timely, conclusions supported by the data and the BAL sample analysis provides real novel data.

Figure 2: Please designate Figure 2 into two panels: A and B, since it is later referred to in this way in the text. It would also be helpful to illustrate the scale so one can observe the large disruption of the system. The scale only goes to 5 in both directions, and being able to see the extreme over-expression would improve the argument that components of the BK system are overexpressed.



Subsection “Hyaluronic Acid Synthesis and Degradation”. It would be helpful to add a sentence of two to expand on the pulmonary thrombosis evidence, as it's known that thrombosis is observed in some Covid-19 patients. It could possibly be added in the third paragraph below.

Subsection “Bradykinin Storms: A Model of SARS-CoV-2, COVID-19, and BK-driven Vascular Permeabilization” third paragraph. The HA hypothesis is compelling and potentially explanatory for the hypoxia observed in Covid-19 patients. This hypothesis would be better supported by a representation of the data referenced here (Barton et al., 2020; Xu et al., 2020; Adachi et al., 2020), as opposed to just stating that HA buildup is observed. Either a discussion or even a table would be useful with referenced data.

Same section paragraph five. Here again, it would be useful to represent the studies mentioned here (van de Veerdonk et al., 2020) with similar phenotypic observations to Covid-19. Additional discussion of the data from that paper, or even better the addition of a table with referenced data is suggested. The BK hypothesis is a strong and central hypothesis of this paper and it would be better supported with more than just a statement and a reference.

The results of the ChipSeq analysis should be further described. Most importantly, what is the significance of the binding site within 20 kilobases? It seems like a lot of genomic real estate to make an assertion that there is some effect. Is there any evidence this proximity results in activation or deactivation? If so please provide a reference.

Subsection “Potential Interventions”: Another suggestion here to include a table with suggested interventions -> targets -> drugs -> expected effects.

Supplementary figures S1 and S2 could be represented by single tables and also made available in.xls forms.

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**Prevention:** *Active Immunization:* Vaccines

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- 521)** 2020-07-19 Joyner MJ, Bruno KA, Klassen SA, Kunze KL, Johnson PW, Lesser ER, Wiggins CC, Senefeld JW, Klompas AM, Hodge DO, Shepherd JRA, Rea RF, Whelan ER, Clayburn AJ, Spiegel MR, Baker SE, Larson KF, Ripoll JG, Andersen KJ, Buras MR, Vogt MNP, Herasevich V, Dennis JJ, Regimabal RJ, Bauer PR, Blair JE, van Buskirk CM, Winters JL, Stubbs JR, van Helmond N, Butterfield BP, Sexton MA, Soto JCD, Paneth NS, Verdun NC, Marks P, Casadevall A, Fairweather D, Carter RE, Wright RS. COVID-19 Convalescent Plasma in 20,000 hospitalized patients. Mayo Clin Proc September 2020; 95(9): 1888-1897. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7368917/pdf/main.pdf>
- 522)** 2020-07-22 **Andrus CH**: The Mayo Clinic “Safety Update” should be classified as a completed Phase I trial of COVID-19 convalescent plasma. U.S. Copyright Office, 2020-07-22, TXu002214049. [https://web.archive.org/web/20210904020833/https://cocatalog.loc.gov/cgi-bin/Pwebrecon.cgi?v1=6&ti=1%2C6&Search\\_Arg=andrus+charles+h&Search\\_Code=NALL&CNT=25&PID=cXfFuGrmHQvLVILvfNnt7Yjwh73ImgQ&SEQ=20210512081428&SID=1](https://web.archive.org/web/20210904020833/https://cocatalog.loc.gov/cgi-bin/Pwebrecon.cgi?v1=6&ti=1%2C6&Search_Arg=andrus+charles+h&Search_Code=NALL&CNT=25&PID=cXfFuGrmHQvLVILvfNnt7Yjwh73ImgQ&SEQ=20210512081428&SID=1)
- 523)** 2020-07-28 World Health Organization: WHO Webinar on collection of COVID-19 convalescent plasma. <https://www.who.int/news-room/events/detail/2020/07/28/default-calendar/who-webinar-on-collection-of-covid-19-convalescent-plasma>
- 524)** 2020-07-28 White DB, Angus DC: A proposed lottery system to allocate scarce COVID-19 medications. Promoting fairness and generating knowledge. JAMA 2020 Jul 28; 324 (4): 329-330. <https://jamanetwork.com/journals/jama/fullarticle/2767751>
- 525)** 2020-07-29 Cevik M, Tate M, Lloyd O, Maraolo A, Schafers J, Ho A: SARS-CoV-2, SARS-CoV, and MERS-CoV viral load dynamics, duration of viral shedding, and infectiousness: a systematic review and meta-analysis. (Preprint 7-29-2020) Epub 2020 Nov 19; Lancet Microbe 2021 Jan;2(1):e13-e22. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7837230/pdf/main.pdf>
- 526)** 2020-07-30 Adamy J: Families file first wave of Covid-19 lawsuits against companies over worker deaths—Coronavirus victims and their families allege workplaces failed to protect them. Wall Street Journal 30 Jul 2020. <https://www.wsj.com/articles/families-file-first-wave-of-covid-19-lawsuits-against-companies-over-worker-deaths-11596137454>
- 527)** 2020-07-30 American Red Cross: President Trump visits the American Red Cross. To highlight need for convalescent plasma during COVID-19. <https://www.redcross.org/about->

[us/news-and-events/press-release/2020/red-cross-highlights-need-for-convalescent-plasma-during-covid-19.html](https://www.fda.gov/news-events/press-release/2020/red-cross-highlights-need-for-convalescent-plasma-during-covid-19.html)

- 528) 2020-07-30 Hahn S: Plasma Donation – PSA. (*Appeal by the FDA Commissioner on the same day as the American Red Cross visit by President Trump soliciting patients recovering from COVID-19 to donate COVID-19 Convalescent Plasma.*)  
<https://www.youtube.com/watch?v=PlX15rWdBbY>
- 529) 2020-07-30 Howard Bauchner, M.D., JAMA Editor-in-Chief, Interview of FDA Commissioner, Stephen Hahn, M.D. [https://www.youtube.com/watch?v=UdmaU2-C\\_wE](https://www.youtube.com/watch?v=UdmaU2-C_wE)
- 530) 2020-07-30 McKend E: Dr. Birx: Plasma donations needed as coronavirus cases spike nationwide. <https://spectrumnews1.com/ky/lexington/health/2020/07/30/dr--birx--plasma-donations-needed-as-coronavirus-cases-spike-nationwide>
- 531) 2020-07-31 FDA: Donate COVID-19 plasma.  
<http://web.archive.org/web/20200731065328/https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/donate-covid-19-plasma> First attachment of “Dr. Hahn – Plasma Donation – PSA”,  
<https://www.youtube.com/watch?v=PlX15rWdBbY> [Initially posting April 14, 2020].
- 532) 2020-08-03 AEI: Op-ed, 4 former FDA commissioners: Blood plasma might be the COVID-19 treatment we need. The Washington Post <https://www.aei.org/op-eds/4-former-fda-commissioners-blood-plasma-might-be-the-covid-19-treatment-we-need/>
- 533) 2020-08-03 Alltucker K: ‘We’re in for a bad and rocky ride.’ Ex-WHO doctor who helped eradicate smallpox predicts COVID-19 turmoil for years. USA TODAY, Published 8:15 p.m. ET Aug. 3, 2020 | Updated 1:41 p.m. ET Aug. 4, 2020.  
<https://www.healthleadersmedia.com/covid-19/were-bad-and-rocky-ride-ex-who-doctor-who-helped-eradicate-smallpox-predicts-covid-19>

The world will be fighting coronavirus for the next three to four years as virus hot spots skip from nation to nation, and the pandemic's toll will linger for decades, said Dr. Larry Brilliant, a California epidemiologist who was part of a World Health Organization team in the 1970s that helped eradicate smallpox.

But it's "not all doom and gloom," with effective vaccines likely to emerge from dozens of candidates worldwide and effective treatments, including convalescent plasma and monoclonal antibodies, to help people recover more quickly, said Brilliant, who chairs Ending Pandemics advisory board.

"We will still be chasing the virus four years from now. But it won't be like (today)," Brilliant told the USA TODAY Editorial Board on Monday afternoon. "It will be like the smallpox eradication program. The polio eradication program. Having yellow fever in some countries and not in others."

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**Treatment:** Passive Immunization: COVID-19 Convalescent Plasma and Antibodies and Antivirals  
**Prevention:** Active Immunization: Vaccines

- 534) 2020-08-03 Sharun K, Tiwari R, Iqbal Yattoo M: Patel SK, Natesan S, Dhama J: Antibody-based immunotherapeutics and use of convalescent plasma to counter COVID-19: advances and prospects. Expert Opinion on Biological Therapy. 2020; 20 (9): 1033-1046. <https://www.tandfonline.com/doi/pdf/10.1080/14712598.2020.1796963?needAccess=true>
- 535) 2020-08-04 Thomas K, Weiland N: As Trump praises plasma, researchers struggle to finish critical studies. New York Times <https://www.nytimes.com/2020/08/04/health/trump-plasma.html>
- 536) 2020-08-04 Dockser Marcus A: Convalescent plasma reduced death rate among Covid-19 patients, study data signals—Hospitalized patients who got earlier transfusions of blood plasma rich in antibodies to the coronavirus show a lower mortality rate. Wall Street Journal. <https://www.wsj.com/articles/convalescent-plasma-reduced-death-rate-among-covid-19-patients-study-data-signals-11596594390>

Hospitalized Covid-19 patients who received transfusions of blood plasma rich with antibodies from recovered patients reduced their mortality rate by about 50%, according to researchers running a large national study.

The researchers presented their data analysis Saturday in a webinar for physicians interested in learning about [so-called convalescent plasma](#), with data slides that were reviewed by The Wall Street Journal. The researchers said they saw signs that the treatment might be working in patients who received high levels of antibodies in plasma early in the course of their illness. They based their conclusions on an analysis of about 3,000 patients.

Patients who at three days or less after diagnosis received plasma containing high levels of antibodies against the coronavirus had a mortality rate of 6.6% at seven days after the transfusion. That compared with a mortality rate of 13.3% for patients who got plasma with low levels of antibodies at four days or more after diagnosis. That indicates reduced mortality of about 50%, the researchers said.

At 30 days after transfusion, the mortality rate was reduced by about 36%, investigators reported

- 537) 2020-08-04 Yong E: How the pandemic defeated America. The Atlantic. <https://www.theatlantic.com/magazine/archive/2020/09/coronavirus-american-failure/614191/>
- 538) 2020-08-06 Hegerova L, Gooley TA, Sweerus KA, Maree C, Bailey M, Dunleavy V, Patel K, Alcom K, Haley R, Johnsen JM, Konkle BA, Lahti AC, Alexander ML, Goldman JD, Lipke A, Lim S, Pauk JS, Pagel JM: Use of convalescent plasma in hospitalized patients with COVID-19: case series. Blood 6 August 2020; 136 (6): 759-762. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7414587/pdf/main.pdf>

In conclusion, the current study suggests that CP use in **severe and critically ill patients with COVID-19 may improve survival if given early in the course of disease**. The efficacy as a

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potential therapy needs further study in well-designed trials to better understand the contribution of CP to outcomes in COVID-19.

- 539)** 2020-08-06 Bloch EM: Convalescent plasma to treat COVID-19. Convalescent plasma to treat COVID-19. Blood 6 August 2020; 136 (6): 654-655.

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7414591/pdf/main.pdf>

In conclusion, observational studies and compassionate use programs have been instrumental in the mobilization of CCP to contend with a global health emergency. Although safety has been addressed, efficacy data are critically needed to transition CCP's status from an investigational product to a standard therapy. The latter has practical ramifications, offering a formal mechanism for reimbursement and thus durable treatment strategy. Broadly, COVID-19 presents a rare opportunity to study CP. If shown to be effective, CP would offer a scalable model that could be applied both to the current pandemic as well as to future emerging infectious diseases. It could also facilitate development of hyperimmune globulin and vaccine design. Clinical trials are already under way to address the uncertainty of use. Nonetheless, harmonization of efforts is needed along with creative approaches to overcome looming obstacles, such as pairing of trials of similar design and/or metaanalysis. We must not be left wondering whether the intervention worked after the pandemic wanes.

- 540)** 2020-08-06 Xia X, Li K, Wu L, Wang Z, Zhu M, Huang B, Li J, Wang Z, Wu W, Wu M, Li W, Li L, Cai Y, Bosco B, Zhong A, Liu X, Lv T, Gan Z, Chen G, Pan Y, Liu C, Zhang K, Xu X, Wang C, Wang Q: Improved clinical symptoms and mortality among patients with severe or critical COVID-19 after convalescent plasma transfusion. Blood 6 August 2020; 136 (6): 755-758. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7414593/pdf/main.pdf>

Experience from SARS-CoV-1 shows that convalescent plasma is most effective when administered shortly after symptom onset, typically within 2 weeks.<sup>7,14,17</sup> The study by Liu et al<sup>16</sup> showed that the effect of CCP was similar in an interval of 3 weeks' duration of symptoms. We compared the time to clinical improvement in patients with different therapy timings in our cohort, including 1 to 4 weeks, 5 to 6 weeks, 7 weeks, and ≥8 weeks after symptom onset. The results showed that the median time to clinical improvement was ;10 days in the 1 to 4 weeks', 5 to 6 weeks', and 7 weeks' groups. However, the time to clinical improvement was significantly prolonged in the ≥8 weeks' group (Figure 1I).

In summary, we analyzed a large cohort of patients with COVID19 who received CCP and provide detailed evidence regarding their clinical improvement. Although the homogeneous data obtained from a single center may reduce some biases, there could inevitably be some confounding factors (eg, biased patient assignments) in this retrospective study. In addition, complete data on neutralizing antibody titers in CCP units were not available, limiting the power of evaluating the correlation between the quality of donor plasma and efficacy. Moreover, a stratified analysis of cases of severe and critical patients could not be performed due to the low proportion of critical patients. This analysis differs from existing studies in that its dynamic laboratory observations using large-scale data make it possible to analyze the potential therapeutic mechanism of CCP, recognize the characteristics of responders and nonresponders, and identify the indications and timing of therapy.<sup>18</sup> Our results suggest that CCP, transfused even after 2 weeks (median of 45 days in our cohort) of symptom onset, could improve the symptoms and mortality in patients with severe or critical cases of COVID-19. We anticipate that this study could shed new light in clinical practice and monoclonal antibody development for COVID-19.

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- 541) 2020-08-06. Tobian AA, Shaz BH: Earlier the better: convalescent plasma. Blood 6 August 2020; 136 (6): 652-653.

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7414595/pdf/main.pdf>

Convalescent plasma is one of the best therapies currently available to treat COVID-19. However, critical questions on timing of treatment in the disease course and dose (volume and antibody titer levels) need to be answered. These answers will also help prepare us for other passive antibody treatments (eg, hyperimmune globulin made from convalescent plasma and monoclonal antibodies). The medical community must work together to battle this deadly disease in order to determine the best therapies and reduce mortality.

- 542) 2020-08-07 U.S. Food & Drug Administration: Donate COVID-19 Plasma.

<http://web.archive.org/web/20200816041956/https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/donate-covid-19-plasma>

- 543) 2020-08-12 Kozlov M: Two Washington U. doctors lead national effort to study new COVID-19 treatment. St. Louis Post-Dispatch Aug 12, 2020.

[https://www.stltoday.com/lifestyles/health-med-fit/coronavirus/two-washington-u-doctors-lead-national-effort-to-study-new-covid-19-treatment/article\\_ccec0f56-4493-5a26-8601-45e35d364b2d.html](https://www.stltoday.com/lifestyles/health-med-fit/coronavirus/two-washington-u-doctors-lead-national-effort-to-study-new-covid-19-treatment/article_ccec0f56-4493-5a26-8601-45e35d364b2d.html)

Since April, the Trump administration has set aside **more than \$300 million** to collect plasma and, with the Mayo Clinic, launch an experimental drug program, serving high-risk patients with few other treatment options. More than 60,000 have received plasma.

But the program has also had an unintended consequence: Patients aren't signing up for controlled trials, which compare outcomes for patients randomly assigned to receive the treatment with those who receive a placebo.

"If you have a 50% chance of getting either the stuff or nothing, which would you choose?" said Grossman, who is also director of transfusion medicine at Barnes-Jewish Hospital.

Moreover, clinical trials require thousands of patients, but the virus is spiking so quickly in communities, by the time doctors set up a trial, patients have disappeared.

- 544) 2020-08-12 Joyner MJ, Senefeld JW, Klassen SA, Mills JR, Johnson PW, Theel ES, Wiggins CC, Bruno KA, Klompas AM, Lesser ER, Kunze KL, Sexton MA, Soto JCD, Baker SE, Shepherd JRA, van Helmond N, van Buskirk CM, Winters JL, Stubbs JR, Rea RF, Hodge DO, Herasevich V, Whenlan ER, Clayburn AJ, Larson KF, Ripoll JG, Andersen KJ, Buras MR, Vogt MNP, Dennis JJ, Regimbal RJ, Bauer PR, Blair JE, Paneth NS, Fairweather DL, Wright RS, Carter RE, Casadevall A: Effect of convalescent plasma on mortality among hospitalized patients with COVID-19: Initial three-month experience. Version 1. medRxiv Preprint. 2020 Aug 12.

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7430623/?report=printable>

**Abstract** ...Participants: Adult participants enrolled and transfused under the purview of the US Convalescent Plasma EAP program between April 4 and July 4, 2020 who were hospitalized with (or at risk of) severe or life threatening acute COVID-19 respiratory syndrome. Intervention: Transfusion of at least one unit of human COVID-19 convalescent plasma using standard transfusion guidelines at any time during hospitalization. Convalescent plasma was donated by recently-recovered COVID-19 survivors, and the antibody levels in the units collected were unknown at the time of transfusion. Main Outcomes and Measures: Seven and thirty-day mortality. Results: the 35,322 transfused patients had heterogeneous demographic and clinical characteristics. This cohort included a high proportion of critically-ill patients, with 52.3% in the intensive care unit (ICU) and 27.5% receiving mechanical ventilation at the time of plasma transfusion. The seven-day mortality rate was 8.7% [95% CI 8.3-9.2%] in patients transfused within 3 days of COVID-19 diagnosis but 11.9% [11.4%-12.2%] in patients transfused 4 or more days after diagnosis ( $p < 0.0001$ ).

- 545)** 2020-08-17 U.S. Food & Drug Administration: Donate COVID-19 Plasma.  
<http://web.archive.org/web/20200822062658/https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/donate-covid-19-plasma>
- 546)** 2020-08-19 U.S. Food & Drug Administration: Recommendations for Investigational COVID-19 Convalescent Plasma. August 19, 2020.  
<https://web.archive.org/web/20200822210941/https://www.fda.gov/vaccines-blood-biologics/investigational-new-drug-ind-or-device-exemption-ide-process-cber/recommendations-investigational-covid-19-convalescent-plasma>
- 547)** 2020-08-20 Xie J, Wu W, Li S, Hu Y, Hu M, Li J, Yang Y, Huang T, Zheng K, Wang Y, Kang H, Huang Y, Jiang L, Zhang W, Zhong M, Sang L, Zheng X, Pan C, Zheng R, Li X, Tong Z, Qui H, Du B: Clinical characteristics and outcomes of critically ill patients with novel coronavirus infectious disease (COVID-19) in China: a retrospective multicenter study. *Intensive Care Med* 2020 Aug 20; 46: 1863-1872.  
<https://link.springer.com/article/10.1007%2Fs00134-020-06211-2>
- 548)** 2020-08-11 Meini S, Zanichelli A, Sbromavacca R, Luri F, Roberts AT, Suffritti C, Tascini C: Understanding the pathophysiology of COVID-19: Could the contact system be the key? *Frontiers in immunology*.  
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7432138/pdf/fimmu-11-02014.pdf>
- 549)** 2020-08-20 Pharmaceutical Technology: Roche teams up with Regeneron on Covid-19 therapy. <https://www.pharmaceutical-technology.com/news/roche-regeneron-covid-therapy/>
- 550)** 2020-08-21 Hansen J, Baum A, Pascal KE, Russo V, Giordano S, Wloga E, Fulton BO, Yan Y, Koon K, Patel K, Chung KM, Hermann A, Ullman E, Cruz J, Rafique A, Huang T, Fairhurst J, Libertiny C, Malbec M, Lee W, Welsh R, Farr G, Pennington S, Deshpande D, Cheng J, Watty A, Bouffard P, Babb R, Levenkova N, Chen C, Zhang B, Romero Hernandez A, Saotome K, Zhou Y, Franklin M, Sivapalasingam S, Chien Kye D, Weston S, logue J, Haupt R, Frieman M, Chen G, Olson W, Murphy AJ, Stahl N, Yancopoulos GD, Kyrtatsous CA: Studies in humanized mice and convalescent humans yield a SARS-CoV-2 antibody

cocktail. Science 2020; 369 (6506): 1010-1014.  
<https://science.sciencemag.org/content/369/6506/1010>

- 551) 2020-08-23 Trump D: Donald Trump August 23 White House COVID-19 Press Conference Transcript. Rev Aug 23, 2020. Video of the conference:  
<https://www.youtube.com/watch?v=nE0EkrEICRk> Transcript:  
<https://www.rev.com/blog/transcripts/donald-trump-august-23-white-house-covid-19-press-conference-transcript>

### **Appendix 1 of a draft cover letter (never sent) to the President Biden of August 2021:**

Transcript of August 23, 2021 White House press conference in its entirety:  
<https://www.rev.com/blog/transcripts/donald-trump-august-23-white-house-covid-19-press-conference-transcript>

(The video of the August 23, 2020 White House press conference in its entirety:  
<https://www.youtube.com/watch?v=nE0EkrEICRk> )

*President Donald Trump held an August 23 coronavirus press conference where he announced the FDA is issuing an emergency authorization for a COVID-19 treatment called convalescent plasma. Trump touted the approval as a "historic announcement." Read the full transcript of the press conference here.*

Donald Trump: (01:38)

Thank you very much, and it's good to see you all. Hope you had a great weekend at your convention. We're going to have a great convention coming up, and I look forward to it.

Donald Trump: (01:51)

But before I discuss a very historic breakthrough in our fight against the China virus, I'd like to provide an update on the recent wildfires in California and the storms in the Gulf of Mexico. Yesterday, I approved a major disaster declaration for California, spoke to Governor Newsom as they battled two of the worst wildfires in the history of their state. That continues.

Donald Trump: (02:19)

The federal government has already deployed over 26,000 first responders and personnel to battle the wildfires. We're working very closely with the Governor and very closely with a lot of great state representatives and local representatives. We'll take care of the situation, but we have 26,000 first responders already. Our hearts go out to the thousands of families who have lost their homes, as we grieve for the families of two first responders and five residents who have tragically lost their lives in a very horrific fire, one of the biggest we've ever seen.

Donald Trump: (03:01)

My administration is also closely monitoring Hurricane Marco and Tropical Storm Laura, which are coming in rapidly. Hurricane Marco is expected to make landfall in Louisiana tomorrow, and Tropical Storm Laura is expected to hit Louisiana two days later. This is somewhat unprecedented, the scope of the storms, and also the fact that they come so quickly after one another. Both storms have the potential of gathering strength before they make landfall and could cause significant damage across the Gulf Coast and also in Puerto Rico. We have everybody stationed and ready to go in Puerto Rico and the Gulf Coast. We

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have tremendous, tremendous people. FEMA is lined up. We have the Coast Guard ready. The Coast Guard has done a fantastic job. They do such good work, and we want to thank our great Coast Guard.

Donald Trump: (03:58)

I'm asking all Americans in the storm's path to follow the instructions of your state and local governments very closely. I've approved emergency declarations for Puerto Rico and for Louisiana. FEMA is mobilized on the ground and is ready to help. They will be in there very quickly, very, very quickly. I spoke to Governor John Bel Edwards also of Louisiana, and I've informed him, and at his request also, a major disaster declaration is signed and ready to go. We have everybody ready in Puerto Rico, the Gulf Coast, Louisiana, and also on the forest fires in California. We have a great team. Unfortunately, we have some very, very powerful natural disasters.

Donald Trump: (04:47)

On the therapeutics front, this is what I've been looking to do for a long time. This is a great thing. Today, I'm pleased to make a truly historic announcement in our battle against the China virus that will save countless lives. The FDA has issued an Emergency Use Authorization, and a that's such a powerful term, Emergency Use Authorization, for a treatment known as convalescent plasma. This is a powerful therapy that transfuses very, very strong antibodies from the blood of recovered patients to help treat patients battling a current infection. It's had an incredible rate of success. Today's action will dramatically expand access to this treatment.

Donald Trump: (05:39)

I want to thank Dr. Hahn and Secretary Azar. I want to thank the FDA, all of the people that have been working very hard on this. It showed tremendous potential. It's only made possible because of Operation Warp Speed. That is everybody working together. We're years ahead of approvals that we would be if we went by the speed levels of past administration. We'd be two years, three years behind where we are today, and that includes on vaccines that you'll be hearing about very soon, very shortly.

Donald Trump: (06:16)

To deliver treatments and vaccine to save lives, we're removing unnecessary barriers and delays, not by cutting corners, but by marshaling the full power of the federal government. We provided \$48 million to fund the Mayo Clinic study that tested the efficacy of convalescent plasma for patients with the virus. Through this study over 100,000 Americans have already enrolled to receive this treatment, and it is proven to reduce mortality by 35%. It's a tremendous number. The FDA, MIT, Harvard, and Mount Sinai Hospital have also found convalescent plasma to be a very effective method of fighting this horrible disease. Based on the science and the data, the FDA has made the independent determination that the treatment is safe and very effective.

Donald Trump: (07:12)

Recently, we provided up to \$270 million to the American Red Cross and America's blood centers to support the collection of up to 360,000 units of plasma. In late July, we launched a nationwide campaign to ask patients who have recovered, and these are patients that have been incredible the way they've donated. But these are people recovered from the virus to donate plasma. Since then, weekly plasma donations have doubled. Today, I once again urge all Americans who have recovered from the virus to go to coronavirus.gov and sign up and donate plasma today, please. It's been really an incredible ... Just incredible people. The country has united so strongly behind this.

Donald Trump: (08:08)

I'll go over the numbers, but if you look at what's happened and the success that we've had that people don't talk about, the United States has experienced the lowest case fatality rate of any major country in the world. You don't hear that. The European Union's case fatality



rate is estimated to be three times higher than that in the United States. Europe has seen 33% more fatalities compared to a typical non-pandemic year than the United States.

Donald Trump: (08:38)

I just want to ask two of our people that have done such a fantastic job, Alex Azar and Stephen Hahn to say a few words. Stephen, I want to thank you because the FDA really stepped up and especially over the last few days in getting this done. The results have been incredible, and I think you'll see the results even go up very substantially. So we appreciate it. And maybe I'll ask Alex to go first, and then Stephen. Thank you very much, Alex.

Alex Azar: (09:06)

Well, thank you very much, Mr. President. Thanks for the bold leadership that allowed us to deliver this very happy news today. Thanks to your all-of-America approach, America has done more than any other country to expand the arsenal that we have to battle COVID-19. Thanks to early efforts by your administration, Americans have broader access to these treatments, including convalescent plasma, than patients anywhere else in the world.

Alex Azar: (09:33)

In early April, early in our fight against COVID-19, the FDA, BARDA, the Mayo Clinic, and other partners sprang into action to set up an expanded access protocol for this promising treatment. President Trump is the right-to-try President, and he's fought hard to ensure that Americans can have access to promising COVID-19 treatments. Convalescent plasma has been a tried-and-true therapeutic method in prior outbreaks, but the President wanted to ensure that we develop the data to support its use. This FDA authorization is one result of that effort.

Alex Azar: (10:06)

The data we gathered suggests that patients who were treated early in their disease course, within three days of being diagnosed with plasma containing high levels of antibodies, benefited the most from treatment. We saw about a 35% better survival in the patients who benefited most from the treatment, which were patients under 80, who were not on artificial respiration. I just want to emphasize this point because I don't want you to gloss over this number. We dream in drug development of something like a 35% mortality reduction. This is a major advance in the treatment of patients. This is a major advance.

Alex Azar: (10:51)

Convalescent plasma is one new tool that we've added to our arsenal against COVID-19 alongside remdesivir, steroids, and a number of other promising options currently being studied. Because of the President's Operation Warp Speed, we expect to have other new results and new options reaching patients as soon as this fall. Operation Warp Speed is supporting experimental therapeutics all the way through to manufacturing, so that if they meet FDA's gold standard for safety and efficacy, they can begin reaching patients without a day wasted.

Alex Azar: (11:24)

Americans who have tested positive for and recovered from COVID-19 can go to coronavirus.gov to find out a quick, convenient way to play a potentially lifesaving role in our fight. Know if you donate plasma, you could save a life. We've also provided guidance, so healthcare providers can contact patients who have recovered from COVID-19 and give them information on how they can donate.

Alex Azar: (11:48)

So thank you again, Mr. President for supporting this remarkable progress against COVID-19, and I want to thank Dr. Hahn, Dr. Marks, and the entire team at the FDA for the speed

with which they've approached this, the diligence to ensure that this meets the standards at FDA. I'll turn it over to Dr. Hahn, if it's okay, Mr. President.

Donald Trump: (12:07)

[crosstalk 00:12:07] thank you very much. Please, Doctor?

Dr. Hahn: (12:09)

Thank you, Mr. President-

Donald Trump: (12:10)

[crosstalk 00:12:10].

Dr. Hahn: (12:10)

... for your leadership. It's good to be here today to announce FDA's recent decision. From the beginning of this pandemic, the President has asked FDA to cut back red tape to try to speed medical products into the hands of providers, patients, and American consumers. I just want to echo the President's thanks to the more than the 17,000 men and women who work at FDA. They have worked day and night to, in fact, do that.

Dr. Hahn: (12:36)

Plasma is the liquid portion of the blood. That liquid portion contains the natural immunity that someone develops in response to an infection, in this case COVID-19. That liquid portion can be extracted. And for many years, as the President and Secretary Azar said, has been given to patients with infectious diseases for more than a hundred years. So there was a really good rationale for why this might work. In fact, as was mentioned, in early April, an expanded access program was started at the Mayo Clinic with the support of the federal government under President Trump's leadership. That has gone on for the last four months. More than 90,000, close to 100,000, Americans have enrolled in this program, and over 70,000 have received treatment. This is one of the largest expanded access programs in the history of FDA. So a very successful approach to evaluating how convalescent plasma would work.

Dr. Hahn: (13:34)

In the independent judgment of experts and expert scientists at FDA who have reviewed the totality of data, not just the data from this expanded access program, but more than a dozen published studies, as well as the historical experience associated with this, those scientists have concluded that COVID-19 convalescent plasma is safe and shows promising efficacy, thereby meeting the criteria for an emergency use authorization. In the optimal patients, as described by secretary Azar, treated with convalescent plasma at the highest titers, there was a 35% improvement in survival, which is a significant clinical benefit. Now, we're waiting for more data. We're going to continue to gather data, but this clearly meets the criteria that we've established for emergency use authorization, and we're very pleased with these results.

Dr. Hahn: (14:27)

Let me just put this in perspective. Many of you know I was a cancer doctor before I became FDA commissioner, and a 35% improvement in survival is a pretty substantial clinical benefit. What that means is, and if the data continue to pan out, 100 people who are sick with COVID-19, 35 would have been saved because of the administration of plasma. We've seen a great deal of demand for this from doctors around the country. What this emergency use authorization today does, it allows us to continue that and meet the demand.

Dr. Hahn: (15:00)

Again, I want to echo the President's and the Secretary's ask of the American people. If you've recovered from COVID-19, please donate. It could save a life. Mr. President, thank you again.

Donald Trump: (15:11)

Thank you very much, Stephen. I appreciate it.

Speaker 6: (15:18)

Mr. President?

Donald Trump: (15:19)

Okay, any questions?

Speaker 6: (15:19)

Mr. President? Mr. President?

Speaker 7: (15:19)

Thank you, Mr. President. I want to first ask you about the COVID-19 drugs that are in phase three.

Donald Trump: (15:23)

[crosstalk 00:15:24].

Speaker 7: (15:24)

Are they going to be available to the American population on ... You and I talked previously about this idea of right to try.

Donald Trump: (15:32)

Right.

Speaker 7: (15:33)

Can we assure the American people that if it's being studied and it's in phase three, you have that right?

Donald Trump: (15:38)

That's a great question, and I'm not sure a lot of people have been thinking about right to try. We're all waiting for the final answer. Maybe I could ask Stephen, but I would say that right to try is exactly ... If somebody is virtually terminal, in other words they're not going to make it, and if we have these incredible therapies and drugs that are happening, Alex, I think it's a very interesting question. I congratulate you for that question because I think we're-

Speaker 7: (16:05)

Thanks, Mr. President.

Donald Trump: (16:05)

... all waiting for that exact final endpoint. What about that, Stephen? We have all of these seemingly great answers that are ready to come out, but because of the process, it takes a little- Can we use some of this early under Right to Try? Please.

Dr. Hahn: (16:18)

So it's a really good question. Of course, it all depends on the clinical circumstances and what a doctor and a patient together decide with respect to the administration of any agent.

**Dr. Hahn: (16:29)**

But if you think about what happened with convalescent plasma and the expanded access program, this is exactly what happened. We have ongoing clinical trials that are randomized between placebo or an inactive substance and the convalescent plasma. While that was going on, we knew that there was great demand from patients and doctors. The expanded access program is a way of actually doing that and fits perfectly with what the President just said about allowing people to be able to use something that **we have now determined to be very safe.**

Donald Trump: (16:57)

I think it was something we have to really consider very strongly.

Dr. Hahn: (17:00)

Yes, sir.

Donald Trump: (17:00)

I think it's fantastic. You should get credit for that.

Speaker 7: (17:04)

Thanks, Mr. President.

Donald Trump: (17:04)

Thank you. That's very good.

Speaker 8: (17:04)

Mr. President?

Donald Trump: (17:04)

Please, in the back. [OEN 00:17:08]?

Speaker 9: (17:10)

Thank you Mr. President. Convalescent plasma as a treatment has been around for nearly a hundred years. You mentioned Operation Warp Speed, which enabled this process to move along a lot faster. What went into the effort for this to be approved for COVID-19? And was that holdup political in nature?

Donald Trump: (17:30)

Well, I think that there might have been a holdup, but we broke the logjam over the last week, to be honest. I think that there are people in the FDA and actually in your larger department that can see things being held up and wouldn't mind so much. That's my opinion, a very strong opinion. And that's for political reasons. This has nothing to do with politics. This has to do with life or death. So we are being very strong, and we are being very forthright. We have got some incredible answers, and we're not going to let them be held up because every day is lives, and we're not going to let that happen. Okay? Very good, thank you.

Speaker 10: (18:06)

Mr. President?

Donald Trump: (18:06)

Please, go ahead.

Speaker 11: (18:10)

Mr. President, in announcing this today, you said that the FDA has made the independent determination that the treatment is **safe** and very effective. Yet Dr Hahn just said it was showing promising efficacy. Which of the two is correct?

Donald Trump: (18:25)

Well, I think I'll let Dr. Hahn answer that question.

Dr. Hahn: (18:29)

Under our legal authority for Emergency Use Authorization, this is not the same as an approval, but it's an authorization, and it allows us to expand the access to this. We know we're going to continue to collect data. We knew that for all of our Emergency Use Authorizations.

Dr. Hahn: (18:44)

So, for example, remdesivir, which was approved or authorized on May 1st, we're still collecting data, and we will continue to do that with plasma as well. So it's the nuances of the language around the authorization that we use and the legal aspect too.

Speaker 11: (18:57)

It's a promising treatment. You couldn't say it's very effective just yet.

Dr. Hahn: (19:02)

If you're one of those 35 out of 100 people who these data suggest or show survive as a result of it, this is pretty significant for that person and their family.

Donald Trump: (19:12)

Okay, this is a very big day. It's a day we've been looking forward to. Thank you very much. Great questions.

Speaker 12: (19:18)

Was there pressure on you, Dr. Hahn, to authorize this?

Speaker 13: (19:18)

Dr. Hahn?

Speaker 14: (19:18)

Mr. President [crosstalk 00:19:19]

Speaker 12: (19:19)

Dr. Hahn. Could you answer that question? [crosstalk 00:19:19] Dr. Hahn, to authorize this.

Speaker 12: (19:21)

(silence)

**552)** 2020-08-23 Hahn S: Dr. Hahn discussing convalescent plasma at White House News conference. <https://www.facebook.com/FDA/videos/dr-hahn-convalescent-plasma-eua/350991072605290/> goes directly to [Dr. Hahn - Convalescent Plasma EUA \(facebook.com\)](https://www.facebook.com/FDA/videos/350991072605290/) (<https://www.facebook.com/FDA/videos/350991072605290/>) Dr. Hahn's words that follow are extremely important because of what resulted:

By stating that the data was not just from the Mayo Clinic/(FDA) expanded access program as you will note below, Dr. Hahn justified that the issuing of the EUA was completely appropriate. But, in so doing, availability of COVID-19 convalescent plasma from any of the previous Expanded Access Programs was now *de facto* completely suspended / interrupted.

So, in the independent judgment of experts and expert scientists at FDA, who have reviewed the totality of data – not just the data from this expanded access program but more than a dozen published studies as well as the historical experience associated with this – those scientists have concluded that COVID-19 convalescent plasma is safe and shows promising efficacy thereby meeting the criteria for an emergency use authorization.

**553)** 2020-08-23 Hinton DM: U.S. Food & Drug Administration Emergency Utilization Authorization (EUA) Letter to Robert P. Kadlec, MD, MTM&H, MS, Assistant Secretary for Preparedness and Response, issuing the EUA on COVID-19 Convalescent Plasma, August 23, 2020.  
<https://web.archive.org/web/20200823220439/https://www.fda.gov/media/141477/download>

**Current data suggest the largest clinical benefit is associated with high-titer units administered early in the course of disease.** COVID-19 convalescent plasma units containing antibodies to SARS-CoV-2 but not qualified as high-titer by a test found acceptable for this purpose by FDA (see Section II) are considered Low Titer units by a test found acceptable for this purpose by FDA (see Section II) are considered Low Titer units and are acceptable for use based on an individual assessment of patient benefit-risk....

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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*  
**Prevention:** *Active Immunization:* Vaccines



**554) 2020-08-23 FDA News Release: FDA issues emergency use authorization for Convalescent Plasma as potential promising COVID-19 treatment, another achievement in Administration's fight against pandemic. U.S. Food & Drug Administration.**  
<https://www.fda.gov/news-events/press-announcements/fda-issues-emergency-use-authorization-convalescent-plasma-potential-promising-covid-19-treatment>

Today, the U.S. Food and Drug Administration issued an emergency use authorization (EUA) for investigational convalescent plasma for the treatment of COVID-19 in hospitalized patients as part of the agency's ongoing efforts to fight COVID-19. Based on scientific evidence available, the FDA concluded, as outlined in its [decision memorandum](#), this product may be effective in treating COVID-19 and that the known and potential benefits of the product outweigh the known and potential risks of the product.

Today's action follows the FDA's extensive review of the science and data generated over the past several months stemming from efforts to facilitate emergency access to convalescent plasma for patients as clinical trials to definitively demonstrate safety and efficacy remain ongoing. The EUA authorizes the distribution of COVID-19 convalescent plasma in the U.S. and its administration by health care providers, as appropriate, to treat suspected or laboratory-confirmed COVID-19 in hospitalized patients with COVID-19.

**Alex Azar, Health and Human Services Secretary:**

"The FDA's emergency authorization for convalescent plasma is a milestone achievement in President Trump's efforts to save lives from COVID-19," said Secretary Azar. "The Trump Administration recognized the potential of convalescent plasma early on. Months ago, the FDA, BARDA, and private partners began work on making this product available across the country while continuing to evaluate data through clinical trials. Our work on convalescent plasma has delivered broader access to the product than is available in any other country and reached more than 70,000 American patients so far. We are deeply grateful to Americans who have already donated and encourage individuals who have recovered from COVID-19 to consider donating convalescent plasma."

**Stephen M. Hahn, M.D., FDA Commissioner:**

"I am committed to releasing safe and potentially helpful treatments for COVID-19 as quickly as possible in order to save lives. We're encouraged by the early promising data that we've seen about convalescent plasma. The data from studies conducted this year shows that plasma from patients who've recovered from COVID-19 has the potential to help treat those who are suffering from the effects of getting this terrible virus," said Dr. Hahn. "At the same time, we will continue to work with researchers to continue randomized clinical trials to study the safety and effectiveness of convalescent plasma in treating patients infected with the novel coronavirus."

*Scientific Evidence on Convalescent Plasma*

Based on an evaluation of the [EUA criteria](#) and the totality of the available scientific evidence, the FDA's Center for Biologics Evaluation and Research determined that the statutory criteria for issuing an EUA criteria were met.

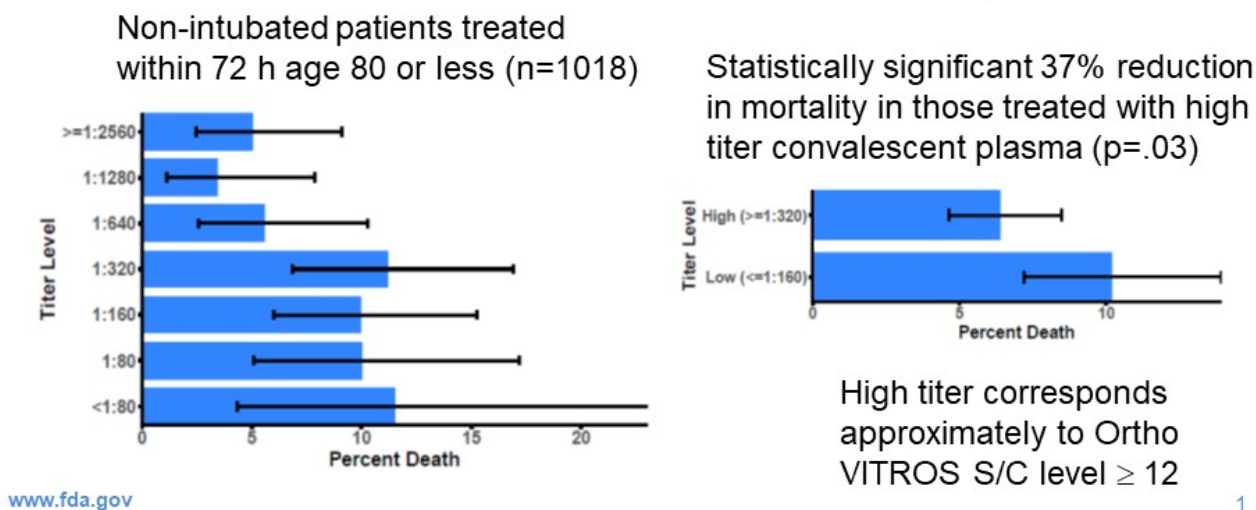
The FDA determined that it is reasonable to believe that COVID-19 convalescent plasma may be effective in lessening the severity or shortening the length of COVID-19 illness in some hospitalized patients. The agency also determined that the known and potential benefits of the product, when used to treat COVID-19, outweigh the known and potential risks of the product and that there are no adequate, approved, and available alternative treatments.

The EUA is not intended to replace randomized clinical trials and facilitating the enrollment of patients into any of the ongoing randomized clinical trials is critically important for the definitive demonstration of safety and efficacy of COVID-19 convalescent plasma. The FDA continues to recommend that the designs of ongoing randomized clinical trials of COVID-19 convalescent plasma and other therapeutic agents remain unaltered, as COVID-19 convalescent plasma does not yet represent a new standard of care based on the current available evidence.

The EUA remains in effect until the termination of the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biologics for prevention and treatment of COVID-19. The EUA may be revised or revoked if it is determined the EUA no longer meets the statutory criteria for issuance.



# COVID-19 Convalescent Plasma Reduction in Death at 7 Days



The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products

- 555) 2020-08-23 U.S. Food & Drug Administration: Clinical Memorandum. COVID-19 Convalescent Plasma EUA Decision Memo. <https://www.fda.gov/media/141480/download> is the baseline URL which when placed in the Wayback Machine, 8-23-2020 to 2-2021 is the same memo on CCP EUA issued 8-23-2020: <https://web.archive.org/web/20200823223716/https://www.fda.gov/media/141480/download>
- 556) 2020-08-23 U.S. Food & Drug Administration: Recommendations for Investigational COVID-19 Convalescent Plasma. August 23, 2020. <https://web.archive.org/web/20200901081726/https://www.fda.gov/vaccines-blood-biologics/investigational-new-drug-ind-or-device-exemption-ide-process-cber/recommendations-investigational-covid-19-convalescent-plasma>
- 557) 2020-08-23 U.S. Food & Drug Administration: Donate COVID-19 Plasma. <http://web.archive.org/web/20201021220421/https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/donate-covid-19-plasma>

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**Treatment:** Passive Immunization: COVID-19 Convalescent Plasma and Antibodies and Antivirals  
**Prevention:** Active Immunization: Vaccines

- 558) 2020-08-23 Gallagher C: Expanded access program for convalescent plasma discontinues enrollment as FDA authorizes its emergency use. Mayo Clinic News Network, August 23, 2020. <https://newsnetwork.mayoclinic.org/discussion/expanded-access-program-for-convalescent-plasma-discontinues-enrollment-as-fda-authorizes-its-emergency-use/>
- 559) 2020-08-23 Andrus CH: Re: Thousands of Americans are *needless dying* because the FDA is illegally ignoring PL 115-176 – The *Right to Try Law*<sup>1,2</sup> and COVID-19 Convalescent Plasma has NOT been given as Prophylaxis and Early after COVID-19 positivity conversion. **Letter mailed to President Trump and the offices of the U.S. Senate.** [In the attached CD: 06 Appendices A-H copy/01 Dear Members of Congress and President Trump 8\_23\_2020]
- 560) 2020-08-24 Thomas K, Fink S: F.D.A. ‘Grossly misrepresented’ blood plasma data, Scientists say. Many experts—including a scientist who worked on the Mayo Clinic study—were bewildered about where a key statistic came from. *The New York Times* Katie <https://web.archive.org/web/20200825025014/https://www.nytimes.com/2020/08/24/health/fda-blood-plasma.html>
- 561) 2020-08-24 Navarro P: Peter Navarro speaks with reports the day after the EUA announcement regarding COVID-19 Convalescent Plasma. <https://www.c-span.org/video/?475057-101/peter-navarro-speaks-reporters>

...kinds of successes he has last thing I want to do is talk a little bit about this cot convalescent plasma this is a great thing for the American people cob lesson plasma can reduce the mortality rate by 35 percent 35 percent and. If you see controversy in the news. You should think about this. There should absolutely be no controversy about convalescent plasma this is a therapy that's been used across many diseases for many decades the odds of it. Hurting you are close to 0 the odds of it helping you are close to 100 percent the only issue is how much it can help and according to the f.d.a. a 35 percent reduction in mortality so for me this convalescent plasma debate is in some sense a litmus test if you see anybody on c.n.n. or m s n b c or in the Democratic Party question the f.d.a. decision in any way all they are doing is politicizing this issue and at a cost of American lives we cannot afford in this China virus debate to politicize or therapeutics in convalescent class by me if that's like going after Bambi you know this is the most one of the it's proven safe and effective Thank you all right. I'm a huge. Moment. For. You.

Is late in our judgment where we've been trying to do this for weeks simply with. I'm not I'm not I'm not privy to what the decisions were and what the data there was I haven't looked at that but I can I again I tell you this convalescent plasma is not on controversial it's been used for decades across many diseases. The odds of it hurting you are close to 0 the odds of it helping you are close to 100 percent this is the right to try president this is a time when Americans are dying and this is something that can be useful and so so look this timing issue again I think I think it's a way of people trying to politicize what shouldn't be politicized...

- 562) 2020-08-25 Dockser Marcus A: Science Behind Convalescent Plasma for Covid-19 is Clouded by Politics in FDA Authorization. The Wall Street Journal Aug 25, 2020.

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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*  
**Prevention:** *Active Immunization:* Vaccines

[https://www.wsj.com/articles/fda-officials-reject-claims-that-convalescent-plasma-decision-was-politicized-11598362563?mod=article\\_inline](https://www.wsj.com/articles/fda-officials-reject-claims-that-convalescent-plasma-decision-was-politicized-11598362563?mod=article_inline)

- 563) 2020-08-25 Dulipsingh L, Ibrahim D, Schaefer EJ, Crowell R, Deffenderfer MR, William K, Lima C, McKenzie J, Cook L, Puff J, Onoroski M, Wakefield DB, Eadie RJ, Kleiboeker SB, Nabors P, Hussain SA: SARS-CoV-2 serology and virology trends in donors and recipients of convalescent plasma. *Transfus Apher Sci* 2020 Aug 25; 59: 1-6.  
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7446657/pdf/main.pdf>
- 564) 2020-08-26 Dasgupta A: Is a bradykinin storm brewing in COVID-19? Excess of the inflammatory molecule bradykinin may explain the fluid build-up in the lungs of patients with coronavirus infections. Clinical trials of inhibitors are putting this hypothesis to the test. *TheScientist*, August 26, 2020. <https://www.the-scientist.com/news-opinion/is-a-bradykinin-storm-brewing-in-covid-19--67876>
- 565) 2020-08-26 Holland S: Dr. Fauci delivers COVID-19 update at joint Grand Rounds. Office of External Affairs, Uniformed Services University, Aug 26, 2020.  
<https://health.mil/News/Articles/2020/08/26/Dr-Fauci-delivers-COVID-19-update-at-joint-Grand-Rounds?page=6#pagingAnchor>
- 566) 2020-08-26 HISTORY.COM Editors: Dred Scott Case.  
<https://www.history.com/topics/black-history/dred-scott-case>
- 567) 2020-08-28 Hinton D, FDA Chief Scientist: U.S. Food & Drug Administration Emergency Use Authorization (EUA) regarding Remdesivir. Letter from RADM Hinton to Ms Rhoades, Gilead Sciences, Inc.  
<https://web.archive.org/web/20200829175858/https://www.fda.gov/media/137564/download>

Pages 1 – 2:

On May 1, 2020, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for emergency use of Veklury (remdesivir)<sup>3</sup> for the treatment of hospitalized patients with severe 2019 coronavirus disease (COVID-19)<sup>4</sup>, pursuant to Section 564 of the Act. Veklury is a direct acting antiviral drug that inhibits viral RNA synthesis. It is an investigational drug and is not currently approved for any indication.

On August 28, 2020, having concluded that revising this EUA is appropriate to protect the public health or safety under section 564(g)(2) of the Act, FDA is reissuing the May 1, 2020 letter in its entirety with revisions incorporated to expand the authorized use of Veklury by no longer limiting its use to the treatment of patients with severe disease. In addition, the Fact Sheet for Health Care Providers has been revised to provide updated clinical trial results and supporting data.<sup>5</sup> ***(VERY IMPORTANT: This negative statement: "...by no longer limiting its use to the treatment of patients with severe disease..." is obfuscation by the FDA. The positive statement that the FDA failed to state at the time and FDA has never stated is:***

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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*  
**Prevention:** *Active Immunization:* Vaccines

**Veklury (Remdesivir) is indicated most efficaciously in the early treatment of COVID-19 in the viremic phase (best within 72 hours of diagnosis) because it inhibits RNA polymerase replication of the COVID-19 RNA. The justifying REASON for this is: “The active form of remdesivir acts as a nucleoside analog and inhibits the RNA-dependent RNA polymerase (RdRp) of coronaviruses including SARS-CoV-2. Remdesivir is incorporated by the RdRp into the growing RNA product and allows for addition of three more nucleotides before RNA synthesis stalls. ...”** Kocic G, Hillen HS, Tegenov D, Dienemann C, Seitz F, Schmitzova J, Farnung L, Siewert A, Hobartner C, Cramer P: Mechanism of SARS-CoV-2 polymerase stalling by remdesivir. *Nature Communications* (2021)12:279 <https://doi.org/10.1038/s41467-020-20542-0> <https://www.nature.com/articles/s41467-020-20542-0.pdf>

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<sup>1</sup> U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act*, 21 U.S.C. § 360 bbb-3. February 4, 2020.

<sup>2</sup> U.S. Department of Health and Human Services, *Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act*, 21 U.S.C. § 360bbb-3, 85 FR 18250 (April 1, 2020).

<sup>3</sup> The May 1, 2020 EUA referred to the authorized drug as “remdesivir;” however, Gilead subsequently requested, and FDA concurred, that the Fact Sheets be altered to add references to remdesivir’s trade name, “Veklury.” “Veklury” is used in this August 28, 2020 reissued letter.

<sup>4</sup> For purposes of the May 1, 2020 EUA, patients with severe disease were defined as patients with oxygen saturation  $\leq 94\%$  on room air or requiring supplemental oxygen or requiring mechanical ventilation or requiring extracorporeal membrane oxygenation (ECMO).

<sup>5</sup> Prior to this reissuance and pursuant to the conditions of authorization, Gilead had requested, and FDA had concurred with other changes to the Fact Sheets, including but not limited to: (1) clarified dosing and administration

Pages 2-3:

## II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited as follows:

Distribution of the authorized Veklury will be controlled by the United States (U.S.) Government for use consistent with the terms and conditions of this EUA

Gilead will supply Veklury to authorized distributors<sup>7</sup>, or directly to a U.S. government agency, who will distribute to hospitals and other healthcare facilities as directed by the U.S. Government, in collaboration with state and local government authorities, as needed;



The Veklury covered by this authorization will be used only to treat adults and children with suspected or laboratory confirmed COVID-19 administered in an in-patient hospital setting via intravenous (IV) infusion by a healthcare provider; and

The use of Veklury covered by this authorization should be in accordance with the dosing regimens as detailed in the authorized Facts Sheets.

- 568) 2020-08-28 **Andrus CH: Re:** This is a cover letter to the Congressional Staffer who will initially read the attached packet. After you read this cover letter, please bring it to your Chief of Staff so he or she might assess the importance of showing it to the Congressman or Congresswoman for whom you work. **Letter to the Offices of the U.S. House of Representatives.** [In the attached CD: 06 Appendices A-H copy/02 Dear Members of the US House of Representatives 8\_28\_2020]
- 569) 2020-09-01 U.S. Food & Drug Administration: Recommendations for Investigational COVID-19 Convalescent Plasma.  
<https://web.archive.org/web/20200901081726/https://www.fda.gov/vaccines-blood-biologics/investigational-new-drug-ind-or-device-exemption-ide-process-cber/recommendations-investigational-covid-19-convalescent-plasma#Patient%20Eligibility>
- 570) 2020-09-02 U.S. Food & Drug Administration: Recommendations for Investigational COVID-19 Convalescent Plasma. September 2, 2020.  
<https://web.archive.org/web/20201115054330/https://www.fda.gov/vaccines-blood-biologics/investigational-new-drug-ind-or-device-exemption-ide-process-cber/recommendations-investigational-covid-19-convalescent-plasma>
- 571) 2020-09-02 U.S. Food & Drug Administration: Investigational COVID-19 Convalescent Plasma – Guidance for Industry.  
<https://web.archive.org/web/20200904181318/https://www.fda.gov/media/136798/download>
- 572) 2020-09-02 U.S. Department of Defense: Tricare Coverage of certain medical benefits in response to the COVID-19 pandemic. Regulations.gov.  
<https://www.regulations.gov/document/DOD-2020-HA-0050-0001>
- 573) 2020-09-03 Weixel N: White House denies Trump has embraced ‘herd immunity’ strategy to COVID-19. The Hill. <https://thehill.com/policy/healthcare/515025-white-house-denies-trump-has-embraced-herd-immunity-strategy-to-covid>

The White House on Thursday again denied the administration has ever considered a policy of "herd immunity" for COVID-19 infections.

"The herd immunity so-called theory was something made up in the fanciful minds of the media. That was never something that was ever considered here at the White House," press secretary Kayleigh McEnany told reporters during a briefing.

McEnany was responding to reports that new White House pandemic adviser Scott Atlas, a fellow at the conservative Hoover Institution who is not an epidemiologist or infectious diseases expert, had advocated for the Trump administration to lift all restrictions aimed at stopping infections from spreading.

Atlas has publicly downplayed the importance of mask wearing, and has suggested the U.S. shouldn't be testing so many people.

The goal of herd immunity is to get as many "healthy" people infected as possible in order to build widespread resistance, while protecting the most vulnerable populations.

The U.S. has let states take the lead on their own coronavirus strategies, and there has been no centralized response from the White House. The U.S. has recorded more than 6 million COVID-19 infections and more than 186,000 deaths.

White House officials have spent the week denying The Washington Post's report that Atlas has been pushing herd immunity — and that President Trump has been listening.

Trump seemingly referred to herd immunity during an interview with Fox News on Monday.

“Once you get to a certain number, you know — we use the word herd, right?” Trump told Laura Ingraham. “Once you get to a certain number, it’s going to go away.”

On Wednesday, White House coronavirus task force coordinator Deborah Birx said she would not be a part of the administration if Trump believed herd immunity was a viable strategy.

“Neither I, nor anybody in the administration, is willing to sacrifice American lives for herd immunity. We’ll get to herd immunity through a vaccine and that’s the right way to do it,” Birx said.

Despite the denials, the administration's approach to the pandemic has changed.

- **Former deputy national security advisor: 'I think we can' find COVID-...**
  - **Over 100 staff sue Houston Methodist over COVID-19 vaccine requirement**
- The Centers for Disease Control and Prevention shifted its guidelines last week, and no longer recommends asymptomatic people get tested even if they have been exposed to someone with the disease.

The strategy serves to underrepresent the true number of people infected with the virus, but lower case numbers could bolster Trump's reelection chances.

Trump and his top aides have also taken to holding public events without wearing a mask and without requiring attendees to wear them, most notably last week's Republican National Convention speech on the White House lawn.

**574) 2020-09-04 Root H, Bartelt L, Gilligan P: The promise of COVID-19 Convalescent Plasma Therapy. American Society for Microbiology**  
<https://asm.org/Articles/2020/July/The-Promise-of-COVID-19-Convalescent-Plasma-Therap>

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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*  
**Prevention:** *Active Immunization:* Vaccines

- 575) 2020-09-05 Martines RB, Ritter JM, Matkovic E, Gary J, Bollweg BC, Bullock H, Goldsmith CS, Silva-Flannery L, Seixas JN, Reagan-Steiner S, Uyeki T, Denison A, Bhatnagar J, Shieh W, Zaki SR, and COVID-19 Pathology Working Group: Pathology and pathogenesis of SARS-CoV-2 associated with fatal coronavirus disease, United States. CDC, Centers for Disease Control and Prevention: *Emerging Infectious Diseases*. Sept 2020; 26(9): 2005-2015. Doi: 10.3201/eid26009.202095. [https://wwwnc.cdc.gov/eid/article/26/9/20-2095\\_article](https://wwwnc.cdc.gov/eid/article/26/9/20-2095_article)
- 576) 2020-09-08 Lowe D: Bradykinin and the coronavirus. <https://www.science.org/content/blog-post/bradykinin-and-coronavirus>
- 577) 2020-09-15 Simply Wall St: How much does Regeneron Pharmaceuticals' (NASDAQ:REGN) CEO make? <https://simplywall.st/stocks/us/pharmaceuticals-biotech/nasdaq-regn/regeneron-pharmaceuticals/news/how-much-does-regeneron-pharmaceuticals-nasdaqregn-ceo-make>
- 578) 2020-09-15 Kumar M, Al Khodor S: Pathophysiology and treatment strategies for COVID-19. *Journal of Translational Medicine* 15 Sept 2020; 18: 353- 361. <https://link.springer.com/content/pdf/10.1186/s12967-020-02520-8.pdf>
- 579) 2020-09-15 Liu STH, Lin HM, Baine I, Wajnberg A, Gumprecht JP, Rahman F, Rodriguez D, Tandon P, Bassily-Marcus A, Bander J, Sanky C, Dupper A, Zheng A, Altman DR, Chen BK, Krammer F, Rao Mendu D, Firpo-Betancourt A, Levin MA, Bagiella E, Casadevall A, Cordon-Cardo C, Jhang JS, Arinsburg SA, Reich DL, Aberg JA, Bouvier NM. Convalescent plasma treatment of severe COVID-19: A matched control study. medRxiv preprint. Published initially on 2020 September 15 as a medRxiv preprint and subsequently *Nature Medicine* 2020 November; 26: 1708-1713. <https://www.nature.com/articles/s41591-020-1088-9.pdf>

**Abstract Results** Convalescent plasma recipients were more likely than control patients to remain the same or have improvements in their supplemental oxygen requirements by post-transfusion day 14, with an odds ratio of 0.86 (95% CI: 0.75~0.98; p=0.028). Plasma recipients also demonstrated improved survival, compared to control patients (log-rank test: p = 0.039). In a covariates-adjusted Cox model, convalescent plasma transfusion improved survival for non-intubated patients (hazard ratio 0.19 (95% CI: 0.05~0.72); p = 0.015), but not for intubated patients (1.24 (0.33~4.67); p=0.752).

**Mr. President: What the abstract results above mean is that if the patients require intubation (at the end of the Cytokine Cascade and Bradykinin Storm), then there was no survival advantage to Passive Immunization with COVID-19 Convalescent Plasma.--**BUT**, if COVID-19 Convalescent Plasma was given before intubation, in all analyses in this study, there was a significant survival advantage (i.e.: all p values were < 0.05).**

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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*  
**Prevention:** *Active Immunization:* Vaccines

**580)** 2020-09-16 Roth LK: Investigational COVID-19 Convalescent Plasma: Guidance for Industry; Withdrawal of guidance. U.S. Food and Drug Administration, Regulations.gov. Docket (FDA-2020-D-1825). <https://www.regulations.gov/document/FDA-2020-D-1825-0011>

- i. *FDA is withdrawing the guidance for industry entitled “Investigational COVID-19 Convalescent Plasma” (May 2020 guidance) dated April 2020 and updated May 2020. The availability of this guidance was announced in the Federal Register of May 26, 2020, (85 FR 31513) and was posted on FDA’s website on May 1, 2020.*
- ii. *On August 23, 2020, the Agency issued an emergency use authorization (EUA) (available at: <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs>) for COVID-19 convalescent plasma for the treatment of hospitalized patients with COVID-19. Given the issuance of this EUA, FDA is issuing a new guidance of the same title that provides recommendations and additional information related to the EUA for the use of COVID-19 convalescent plasma to treat hospitalized patients with COVID-19. The new guidance supersedes the May 2020 guidance. Elsewhere in this issue of the Federal Register, FDA is announcing the availability of the new guidance.*

**581)** 2020-09-16 European Blood Alliance: Support-E European project on COVID-19 convalescent plasma. EU Commission allocates 4M grant for SUPPORT-E. <https://europeanbloodalliance.eu/activities/convalescent-plasma-cpp/support-e-european-project-on-covid-19-convalescent-plasma/>

**582)** 2020-09-19 Altuntas F, Ata N, Yigenoglu TN, Basci S, Dal MS, Korkmaz S, Namdaroglu S, Basturk A, Hacibekiroglu T, Dogu MH, Berber I, Dal K, Kinik D, Haznedaroglu I, Yimaz FM, Kilic I, Demircioglu S, Yosunkaya A, Erkurt MA, Turgut B, Caglayan M, Celik O: Convalescent plasma therapy in patients with COVID-19. Transfusion and Apheresis Science (60) 2021. 102955 Online September 19, 2020. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7501849/pdf/main.pdf>

**583)** 2020-09-19 Parshley L: This theory might explain “Covid toes” and other mysteries of the disease. Vox <https://www.vox.com/21445038/covid-19-symptoms-treatments-bradykinin-cytokine-storm>

**584)** 2020-09-19 Rahaman M, Li Chen, Yao Y, Kulwa F, Rahman MA, Wang Q, Qi S, Kong F, Zhu X, Zhao X: Identification of COVID-19 samples from chest X-ray images using deep learning: A comparison of transfer learning approaches. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7592691/>

**585)** 2020-09-20 Ibrahim D, Dulipsingh L, Zapatka L, Eadie R, Crowell R, Williams K, Wakefield DB, Cook L, Puff J, Hussain SA: Factors associationed with good patient

outcomes following convalescent plasma in COVID-19: A prospective phase II clinical trial. *Infect Dis Ther* (2020) 9:913-926. <https://europepmc.org/article/med/32983830>

**586)** 2020-09-21 U.S. Department of Health and Human Services, Food and Drug Administration [Docket No. FDA-2020-D-1825]: Investigational COVID-19 Convalescent Plasma; Guidance for Industry; Availability. *Federal Register* / Vol. 85, No. 183 / Monday, September 21, 2020 / Notices, 59319 – 59320. <https://www.govinfo.gov/content/pkg/FR-2020-09-21/pdf/2020-20801.pdf>

**587)** 2020-09-23 Ward H: Number of annual blood plasma collections in the United States from 2007 to 2019. Statista. <https://www.statista.com/statistics/756229/number-of-annual-plasma-collections-in-the-us/>

**588)** 2020-09-23 Selvi V: Review Article: Convalescent plasma: A challenging tool to treat COVID-19 patients—A lesson from the past and new perspectives. *BioMed Research International*. <https://downloads.hindawi.com/journals/bmri/2020/2606058.pdf>

On March 11th, 2020, the World Health Organization declared COVID-19 infection as a pandemic. Since it is a novel virus, there are basically no proven drugs or therapies; although many laboratories in different countries are working to develop a vaccine, it will take time to make it available. Passive immunization is the therapy born from the intuition of Behring and Kisato in the late 19th century. It was widely used for the treatment of bacterial infections until the discovery of antibiotics, as well as during the viral pandemics of the 20th century and of the beginning of the 21st; it still has clinical applications (e.g., tetanus prevention). This paper summarizes the basic principles of passive immunization, with particular reference to convalescent plasma. The literature concerning its use during past epidemics and the results of the first clinical studies concerning its use during the current pandemic are discussed too. A large section is dedicated to the analysis of the possible, although rare, side effects. Recently, in 2017, the WHO Blood Regulators Network (BRN) published a position paper, recommending convalescent plasma as the first choice treatment to be tested in the absence of authorized drugs; however, this strategy has not been followed. In the current epidemic, the principle of passive immunization through convalescent plasma has been applied in several circumstances and particularly in patients with serious complications. The first reported results are encouraging and confirm the effectiveness of plasma therapy and its safety. Also, the FDA has proposed plasma treatment in order to face the increasingly complex situation and manage patients with serious or immediately life-threatening COVID-19 disease. Several studies and clinical programs are still ongoing.

**589)** 2020-09-23 Boehmer TK, DeVies J, Caruso E, van Santen KL, Tang S, Black CL, Hartnett KP, Kite-Powel A, Dietz S, Lorzier M, Cundlapalli AV: Changing age distribution of the COVID-19 Pandemic—United States, May-August 2020. *Morbidity and Mortality Weekly Report*, Centers for Disease Control, U.S. Department of Health and Human Services. <https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm6939e1-H.pdf>

**590)** 2020-09-23 Fara A, Miltrev Z, Rosalia RA, Assas BM: Cytokine storm and COVID-19: a chronicle of pro-inflammatory cytokines. *The Royal Society publishing – Open Biology*. 2020 Sep 23; 10(9): 200160. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7536084/>

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- 591)** 2020-09-25 Parasher A: COVID-19: Current understanding of its pathophysiology, clinical presentation and treatment. Postgrad Med J 2021;97:312-320.  
<https://pmj.bmj.com/content/postgradmedj/97/1147/312.full.pdf>
- 592)** 2020-09-25 Pau AK, Aberg J, Baker J, Baker J, Belperio PS, Coopersmith C, Crew P, Grund B, Gulick RM, Harrison C, Kim A, Lane C, Masur H, Sheikh V, Singh K, Yazdany J, Tebas P, for the National Institutes of Health COVID-19 Treatment Guidelines Panel\*: Convalescent plasma for the treatment of COVID-19: Perspectives of the National Institutes of Health COVID-19 Treatment Guidelines Panel. Ann of Internal Med 2021 Jan; 174 (1): 93-95. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7556653/pdf/aim-olf-M206448.pdf>  
This article was published at Annals.org on 25 September 2020, \* For members of the National Institutes of Health COVID-19 Treatment Guidelines Panel, see the Appendix Table (available at Annals.org). ***[This is such an important article that it has been copied and pasted to follow in its entirety. This is the NIH's justification of merging Phase I (safety) trials with Phase II (efficacy) trials so as to circumvent completely ever applying PL-115-176: The Right to Try Law with regards to COVID-19 Convalescent Plasma but also any future investigational drug or biologic ad infinitum. This obfuscation by the NIH is tantamount to justifying repeated violations of PL-115-176 and is ethically shameful!].***

Currently, no Food and Drug Administration (FDA)–approved therapeutics exist for coronavirus disease 2019 (COVID-19). In this context, the pandemic has put considerable pressure on health care providers to prescribe treatments despite limited information about their safety and efficacy. This pressure has exacerbated the tension between the importance of practicing evidence-based medicine and the urgency of providing access to promising therapies before their safety and efficacy are established.

A strong scientific rationale and historical precedents exist for the study of passive immunotherapeutic approaches for viral infections (4). Concentrated, virus-specific immunoglobulin preparations are FDA approved for the postexposure prophylaxis of such viral infections as hepatitis B, varicella, and rabies (5). Recently, a randomized controlled trial (RCT) demonstrated the efficacy of 2 different monoclonal antibody products for treating Ebola virus disease (6).

On 23 August 2020, the FDA issued an Emergency Use Authorization (EUA) for convalescent plasma for treating COVID-19 (2). An EUA does not constitute drug approval by the FDA. Rather, an EUA allows the FDA to facilitate the availability and unapproved uses of medical products during a public health emergency (3). The criteria for issuing an EUA for medical products include the following: The public health concern must be serious or life threatening; sufficient evidence must exist that the product “may be effective”; the known and potential benefits of the product, when used to diagnose, prevent, or treat the identified disease or condition, outweigh the known and potential risks of the product; and no adequate, approved alternatives to the product are available (3).

A strong scientific rationale and historical precedents exist for the study of passive immunotherapeutic approaches for viral infections (4). Concentrated, virus-specific immunoglobulin preparations are FDA approved for the postexposure prophylaxis of such viral infections as hepatitis B, varicella, and rabies (5). Recently, a randomized controlled trial (RCT)

demonstrated the efficacy of 2 different monoclonal antibody products for treating Ebola virus disease (6).

The situation is less clear regarding the safety and efficacy of convalescent plasma, which has been used to treat viral infections from the 1918 influenza pandemic to the recent epidemics of severe acute respiratory syndrome (SARS), H1N1 influenza, Middle East respiratory syndrome, and Ebola virus disease (7–10). The only RCT demonstrating efficacy of convalescent plasma for an infectious disease was conducted more than 40 years ago, for treating Argentine hemorrhagic fever (11).

Early in the COVID-19 pandemic, convalescent plasma was used in China to treat hospitalized patients with COVID-19 (7). Shortly thereafter, RCTs evaluating convalescent plasma in patients with COVID-19 began in several countries, including the United States (12). In March 2020, the FDA authorized expanded access to convalescent plasma for treating severe or life-threatening COVID-19 under individual-patient emergency Investigational New Drug applications. The Mayo Clinic's Expanded Access Program (EAP) was developed in parallel to provide broader access to convalescent plasma; however, it was not designed to generate definitive data on safety or to evaluate efficacy (13). One of the requirements for an EAP is that it not interfere with pivotal trials (14). Adequately powered RCTs of convalescent plasma in the United States have been slow to enroll patients.

Given the lack of data from properly powered RCTs, and the need to inform regulatory decision making regarding continued access to convalescent plasma, both the FDA and the Mayo Clinic performed retrospective, indirect evaluations of efficacy by using EAP data, hypothesizing that patients who received plasma units with higher titers of neutralizing antibodies would have better clinical outcomes. The results of the analyses were used as supporting evidence for the EUA.

The FDA analysis included 4330 patients, and donor neutralizing antibody titers were measured by the Broad Institute, using a SARS coronavirus 2 (SARS-CoV-2) neutralization assay (15). The analysis revealed no difference in 7-day mortality between the patients who received high-titer and those who received low-titer plasma in the overall population or in the subset of patients who were intubated. However, among nonintubated patients (approximately two thirds of those analyzed), 11% of those who received high-titer plasma died within 7 days of transfusion compared with 14% who received low-titer plasma ( $P = 0.03$ ) (16). In a post hoc analysis of nonintubated patients who were younger than 80 years and treated within 72 hours of diagnosis, 7-day mortality for those who received high- versus low-titer plasma was 6.3% and 11.3%, respectively ( $P = 0.0008$ ) (15).

A similar efficacy analysis by the Mayo Clinic included 3082 participants who had received a single unit of plasma among the 35 322 participants who had received plasma through the EAP by 4 July 2020 (17). Antibody titers were measured by using the VITROS anti-SARS-CoV-2 IgG assay (Ortho Clinical Diagnostics), and outcomes were compared among patients receiving low- (lowest 18%), medium-, and high-titer (highest 17%) plasma. After adjusting for baseline characteristics, the 30-day mortality rate was 29.1% in the low-titer group and 24.7% in the high-titer group. This difference did not reach statistical significance. The Mayo Clinic post hoc subgroup analyses also suggested a benefit of high-titer plasma in patients who received plasma within 3 days of COVID-19 diagnosis (17).

The FDA concluded that the totality of data, including additional data from small randomized trials and nonrandomized, observational, and animal studies, met the criteria for EUA issuance.

Despite clearly meeting the “may be effective” criterion for EUA issuance, the analyses of the EAP data are not sufficient to establish the efficacy or safety of convalescent plasma because of the lack of an untreated control group. For example, the possibility that differences in outcomes are attributable to harm from low-titer plasma rather than benefit from high-titer plasma cannot be excluded. In addition, the EAP data may be subject to several confounders, including regional

differences and temporal trends in COVID-19 management. There is no widely available and generally agreed-upon best test for measuring neutralizing antibodies, and the antibody titers in convalescent plasma from patients who have recovered from COVID-19 are highly variable. In addition, the analyses focused on early mortality, which may not be clinically meaningful in the context of the prolonged disease course of COVID-19. The efficacy analyses rely on a subset of EAP patients and thus represent only a fraction of patients who received plasma through the EAP (17). In this regard, additional analyses of the EAP cohort and completion of the current RCTs will be of critical importance.

Taking everything into account, the Panel has determined that currently the data are insufficient to recommend for or against convalescent plasma for treating COVID-19 (18). Prospective, well-controlled, and adequately powered RCTs are needed to determine whether convalescent plasma and other passive immunotherapies are effective and safe for COVID-19 treatment. Although providers have access to this therapy, the Panel cannot recommend it as a standard of care for treating COVID-19 at this time. This is consistent with the language of the convalescent plasma EUA Fact Sheet (19).

The COVID-19 pandemic has intensified the tension between providing rapid access to promising therapies and generating the scientific evidence needed to establish whether those therapies are safe and effective. This tension was also noted during the West African Ebola outbreak in 2014 to 2016, when several therapies, including convalescent plasma, were claimed to be of benefit. A National Academies of Sciences, Engineering, and Medicine review of that response noted that RCTs are critical during an outbreak, because they are the quickest way to identify effective therapies (20). Experience with convalescent plasma, hydroxychloroquine, and other interventions has taught us that large observational cohorts, EAPs, and EUAs can have a profound impact on our ability to conduct the properly designed RCTs necessary to provide definitive evidence of safety and efficacy. Conversely, the lack of access to large RCTs at many health care centers during the COVID-19 pandemic may exacerbate issues of equity in access to care. Expanded Access Programs continue to be an important mechanism to provide promising therapies for patients who do not otherwise have access to them (that is, through clinical trials). Balancing this tension is challenging but imperative to maintaining the ability to generate rigorous and convincing evidence during a public health crisis.

Despite the challenges of the COVID-19 pandemic, conducting well-controlled, adequately powered RCTs is possible. Two such trials, ACTT (Adaptive COVID-19 Treatment Trial) and RECOVERY (Randomized Evaluation of COVID-19 Therapy), recently demonstrated the efficacy of remdesivir and dexamethasone, respectively, for treating COVID-19 (21, 22). Collaboration and partnership among governmental agencies, industry, academia, and the public are needed to establish and carry out a robust and coordinated emergency research response, including the rapid development, deployment, and analysis of high-caliber RCTs. This approach is the quickest and most efficient way to generate the answers needed to provide the best evidence-based patient care.

- 593)** 2020-09-26 St. Louis Regional Health Commission: History—1970s to 2000s Hospital closures threaten health care safety net. <https://www.stlrhc.org/who-we-are/history/>
- 594)** 2020-09-29 Regeneron: Regeneron’s REGN-COV2 antibody cocktail reduced viral levels and improved symptoms in non-hospitalized COVID-19 patients. While this detailed report by Regeneron to its investors was mentioned in the *Roche Investor Update* of 2020-09-30 <https://www.roche.com/investors/updates/inv-update-2020-09-30.htm> the URL of this report **has been wiped from the Internet site:** <https://investor.regeneron.com/news->

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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*  
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[releases/news-release-details/regenerons-regn-cov2-antibody-cocktail-reduced-viral-levels-and](#) but can be found in its entirety using the Internet Archive (Wayback Machine) <http://web.archive.org/web/20201030083248/https://investor.regeneron.com/news-releases/news-release-details/regenerons-regn-cov2-antibody-cocktail-reduced-viral-levels-and> ***This series of articles have legitimated de facto withholding of the early administration (<72 hours) of Passive Immunization to every American who tested positive going forward. Please note that the following news reports confirmed the existence of the original document:***

Carlson R: COVID-19 antibody cocktail found very effective. Precision Vaccinations, September 30, 2020.  
<https://www.precisionvaccinations.com/covid-19-antibody-cocktail-found-very-effective>

Beasley D: Regeneron says its COVID-19 treatment reduces viral levels, improves symptoms. Reuters APAC September 29, 2020, 9:16 PM.  
<https://www.reuters.com/article/health-coronavirus-treatment-regeneron/regeneron-says-its-covid-19-treatment-reduces-viral-levels-improves-symptoms-idUSKBN26L08A>

CNBC: Regeneron says its coronavirus treatment reduces viral levels, improves symptoms. Published Tue, Sep 29 2020, 4:19; Updated Tue, Sep 29, 2020, 4:41 PM. <https://www.cnn.com/2020/09/29/regeneron-says-its-covid-19-treatment-reduces-viral-levels-improves-symptoms.html>

World Pharma Today: Regeneron's REGN-COV2 antibody cocktail reduced viral levels and improved symptoms in non-hospitalized COVID-19 patients.  
<https://www.worldpharmatoday.com/news/regenerons-regn-cov2-antibody-cocktail-reduced-viral-levels-and-improved-symptoms-in-non-hospitalized-covid-19-patients-2/> The hyperlink contained within this site contains the *verbatim* copy of the missing Regeneron announcement that was accessed by the Wayback Machine above. <https://investor.regeneron.com/news-releases/news-release-details/regenerons-regn-cov2-antibody-cocktail-reduced-viral-levels-and>; attached to this is another URL that summarized the outcomes: <https://c19regn.com/regeneron.html> with the graphic interpretation recorded as 5/12/2021(today) of the outcomes: <https://c19regn.com/r>

September 29, 2020 at 4:01 PM EDT

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## REGENERON'S REGN-COV2 ANTIBODY COCKTAIL REDUCED VIRAL LEVELS AND IMPROVED SYMPTOMS IN NON-HOSPITALIZED COVID-19 PATIENTS

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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*  
**Prevention:** *Active Immunization:* Vaccines

TARRYTOWN, N.Y., Sept. 29, 2020 /PRNewswire/ --

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**Plan rapidly to discuss results with regulatory authorities**

**Regeneron to host investor and media webcast to discuss results at 4:30 pm ET today**

Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) today announced the first data from a descriptive analysis of **a seamless Phase 1/2/3 trial** of its investigational antibody cocktail REGN-COV2 showing it reduced viral load and the time to alleviate symptoms in non-hospitalized patients with COVID-19. REGN-COV2 also showed positive trends in reducing medical visits. The ongoing, randomized, double-blind trial measures the effect of adding REGN-COV2 to usual standard-of-care, compared to adding placebo to standard-of-care.

This trial is part of a larger program that also includes studies of REGN-COV2 for the treatment of hospitalized patients, and for prevention of infection in people who have been exposed to COVID-19 patients.

"After months of incredibly hard work by our talented team, we are extremely gratified to see that Regeneron's antibody cocktail REGN-COV2 rapidly reduced viral load and associated symptoms in infected COVID-19 patients," said George D. Yancopoulos, M.D., Ph.D., President and Chief Scientific Officer of Regeneron. "The greatest treatment benefit was in patients who had not mounted their own effective immune response, suggesting that REGN-COV2 could provide a therapeutic substitute for the naturally-occurring immune response. These patients were less likely to clear the virus on their own, and were at greater risk for prolonged symptoms. We are highly encouraged by the robust and consistent nature of these initial data, as well as the emerging well-tolerated safety profile, and we have begun discussing our findings with regulatory authorities while continuing our ongoing trials. In addition to having positive implications for REGN-COV2 trials and those of other antibody therapies, these data also support the promise of vaccines targeting the SARS-CoV-2 spike protein."

The descriptive analysis included the first 275 patients enrolled in the trial and was designed to evaluate anti-viral activity with REGN-COV2 and identify patients most likely to benefit from treatment; the next cohort, which could be used to rapidly and prospectively confirm these results, has already been enrolled. Patients in the trial were randomized 1:1:1 to receive a one-time infusion of 8 grams of REGN-COV2 (high dose), 2.4 grams of REGN-COV2 (low dose) or placebo. All patients entering the trial had laboratory-confirmed COVID-19 that was being treated in the outpatient setting. Patients were prospectively characterized prior to treatment by serology tests to see if they had already generated antiviral antibodies on their own and were classified as seronegative (no measurable antiviral antibodies) or seropositive (measurable antiviral antibodies). Approximately 45% of patients were seropositive, 41% were seronegative and 14% were categorized as "other" due to unclear or unknown serology status.

- 595) 2020-09-30 Johnson CY:** These laboratory-made antibodies are a best bet for a coronavirus treatment, but there won't be enough. The Washington Post  
<https://www.washingtonpost.com/health/2020/09/30/monoclonal-antibodies-to-treat-covid-19/>

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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*  
**Prevention:** *Active Immunization:* Vaccines



- 596) 2020-10 Behrns KE, Wexner SD: Times are changing and so is *Surgery*. Drs. Behrns and Wexner are the editors-in-chief. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7489221/>
- 597) 2020-10 Abasaed Elhag S, Ibrahim H, Abdelhadi S: Angioedema and urticaria in a COVID-19 patient: A case report and review of the literature. *JAAD Case Reports* 2020 October; 6(10): 1091-1094.  
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7403866/pdf/main.pdf>
- A plausible explanation for the development of angioedema lies in the established **correlation between SARS-CoV-2 and** angiotensin-converting enzyme 2, **a receptor** for the virus to enter the epithelial cells of the lungs. It is known that angiotensin-converting enzyme-2 has a crucial role in the inhibition of des-ARG9 bradykinin, which is a potent ligand of bradykinin receptor 1. Hence, the inhibition of angiotensin-converting enzyme 2 has a crucial role in the inhibition of angiotensin-converting enzyme 2 leads to excessive activation of the bradykinin pathway, and subsequently increases vascular permeability leading to angioedema. This is similar to the proposed mechanism by which this virus causes acute pulmonary edema and acute respiratory distress.
- 598) 2020-10 Ye M, Fu D, Ren Y, Wang F, Wang D, Zhang F, Xia X, Lv T: Treatment with convalescent plasma for COVID-19 patients in Wuhan, China. *J Me Virol*. 2020; 92: 1890-1901. <https://onlinelibrary.wiley.com/doi/epdf/10.1002/jmv.25882>
- 599) 2020-10-01 Hinton D, FDA Chief Scientist: U.S. Food & Drug Administration Emergency Use Authorization (EUA) regarding Remdesivir. Letter from RADM Hinton to Ms Rhoades, Gilead Sciences, Inc.  
<http://web.archive.org/web/20201015193426/https://www.fda.gov/media/137564/download>
- 600) 2020-10-01 Farag YMK: Letter to the Editor: Limitations of safety update on convalescent plasma transfusion in COVID-19 patients. *Mayo Clin Proc* 2020 Dec; 95(12): 2801-2802. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7528833/pdf/main.pdf>
- 601) 2020-10-01 Joyner MJ, Senefeld JW, Klassen SA, Fairweather D, Wright RS: In Reply – Limitations of safety update on convalescent plasma transfusion in COVID-19 patients. *Mayo Clinic Proc* 2020 Dec; 95 (12): 2801-2803.  
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7528832/pdf/main.pdf>
- 602) 2020-10-02 Homer M: Timeline: What we know about Regeneron’s antibody cocktail that was given to President Trump.  
<https://www.khou.com/article/news/health/coronavirus/trump-regeneron-polyclonal-antibody-cocktail/285-636b1f14-fed2-42f3-8b41-0a565a2dd967>

They are “a real best chance of being a game changer,” NIH Director Francis S. Collins told the Washington Post about the experimental drug.

- 603) 2020-10-05 Philippidis A, LeMieux J: Trump's treatments: Regeneron's antibodies and Gilead's Remdesivir explained. Genetic Engineering & Biotechnology News.  
<https://www.genengnews.com/insights/trumps-treatments-regenerons-antibodies-and-gileads-remdesivir-explained/>
- 604) 2020-10-05 LaMonica PR: Trump has ties to drugmaker Regeneron – and now its stock is surging. CNN Business <https://www.cnn.com/2020/10/05/investing/trump-regeneron/index.html>

**New York (CNN Business)** President Trump received a high dose of an experimental antibody cocktail from Regeneron as part of his Covid-19 treatment. Now the drugmaker's stock is up sharply -- and questions are swirling about the president's ties to Regeneron's billionaire CEO.

Trump's team revealed Friday that the president received the drug, called REGN-COV2, which is being used to alleviate symptoms and reduce viral load. Shares of Regeneron surged 7% Monday, bringing the stock's year-to-date gain to more than 60%. The stock reached its highs of the day after Trump tweeted that he will be leaving the hospital Monday evening.

Regeneron CEO Dr. Leonard Schleifer and President Trump are acquainted: The CEO has been a member at Trump's golf club in Westchester, New York, and his company also received \$450 million in government funding in July as part of the president's Operation Warp Speed plan to quickly develop a vaccine and other treatments for Covid-19.

Meanwhile, Trump also recently owned shares of Regeneron (REGN) -- as well as Gilead Sciences (GILD), maker of the antiviral drug remdesivir that the president is also taking. Both stocks were listed as assets on Trump's 2017 filing with the U.S. Office of Government Ethics, though neither were holdings on the president's most recent filing for 2020.

"Len and President Trump are acquaintances from both living in the Westchester area for many years but didn't have any regular contact until this year, when they've discussed matters around Covid on occasion," Regeneron told CNN Business in a statement.

According to Forbes, Schleifer is now worth \$2.5 billion, up from \$2.1 billion in the middle of March. Schleifer primarily donated to Democratic political candidates and PACs in the 2016 and 2018 elections, according to Federal Election Commission records.

Regeneron is one of many biotechs and Big Pharma firms that has skyrocketed on hopes that it may be able to quickly develop an effective coronavirus treatment. The company started human trials for its antibody cocktail in June and began a phase 3 trial just a month later.

It has not yet been approved by the Food and Drug Administration, however. The FDA can approve the administration of it through so-called compassionate use requests on an individual basis. Regeneron confirmed to CNN Business that one of the president's doctors made such a request to Regeneron and the FDA to approve administering the drug to Trump.

Schleifer defended the decision to give Trump the cocktail last week, telling CNN's Wolf Blitzer that Trump "is in a higher-risk group for a variety of reasons" and that "we hope that we will give his immune system enough of a boost so that he can win this and make a complete recovery."

"We've got a lot of data, but we're still in the experimental phase. But when you're in the midst of a pandemic and you have people at risk, we think it makes sense to try these," Schleifer added. Regeneron added in its statement to CNN Business that it is "in discussions with the FDA about potential for an Emergency Use Authorization for REGN-COV2" following the release of positive data about the drug last week.

The company had announced just a few days before President Trump's admission to Walter Reed that its cocktail "reduced viral load and the time to alleviate symptoms in non-hospitalized patients."

Regeneron said it is also in the process of studying the effect of the cocktail on hospitalized patients, as well as whether it can prevent infection in people who have been exposed to Covid-19. Dr. George Yancopoulos, Regeneron's president and chief scientific officer, told CNN's Julia Chatterley in an interview Monday that the company is hoping it can get more doses of REGN-COV2 to patients within the next few months thanks to a partnership with Big Pharma giant Roche.

"We are on track to deliver 300,000 doses by the end of the year and...produce 300,000 doses a month while the demand may even still exceed that," Yancopoulos said. "If the drug is really working and having the effects that we all hope it would, it could be doing a lot of good for a lot of people."

*Correction: An earlier version of this story misstated the compassionate use request process. One of the president's physicians made the request to Regeneron and the FDA.*

605) 2020-10-05 Cohen J: Update: Here's what is known about Trump's COVID-19 treatment. Science <https://www.sciencemag.org/news/2020/10/heres-what-known-about-president-donald-trump-s-covid-19-treatment>

606) 2020-10-05 Gringlas S, Sprunt B: Timeline: What we know of President trump's COVID-19 diagnosis, treatment. NPR. <https://www.npr.org/sections/latest-updates-trump-covid-19-results/2020/10/03/919898777/timeline-what-we-know-of-president-trumps-covid-19-diagnosis>

607) 2020-10-05 Wilt TJ, Kaka AS, MacDonald R, Greer N, Obley A, Duan-Porter: Remdesivir for Adults with COVID-19—A living systematic review for an American College of Physicians Practice Points. Ann Internal Med, Published at Annals.org on 5 October 2020. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7564604/pdf/aim-olf-M205752.pdf>

*[Mr. President, the VA **DID NOT EVEN READ its own publications!** One month after this publication (the abstract is pasted below) and after Velkury (remdesivir) was approved by the FDA on October 22, 2020 as the only licensed drug to this day in the treatment of COVID-19: NDA #21478, the VA Central Office issued **Remdesivir (VELKURY) Criteria for Use, November 2020** limiting use of Velkury (remdesivir) to only: "Inclusion Criteria, The following must be fulfilled in order to meet the criteria for remdesivir: Hospitalized with **SEVERE** COVID-19 [room air oxygen saturation <94%, requiring supplemental oxygen or increase from baseline if on chronic oxygen therapy or is requiring invasive or non-invasive ventilation or ECMO]\*\*\*" ] In December e-mail discussions (see Appendices E of this correspondence) with Richard Stone, M.D., former VHA Chief Medical Executive (former Acting VHA Undersecretary for Health during the early part of your administration), I pointed out this **Significant Directive Error** to Dr. Stone as well as the FDA, the NIH, and the Editors of The New England Journal of Medicine. THIS INCORRECT DIRECTIVE of VA policy CONTINUES EVEN TO THIS DAY, AUGUST 5, 2021, and is ACCESSIBLE ON THE INTERNET as VA policy.] Also, please note the FDA removed the erroneous administration criteria from all its publications on August 28, 2020 and RADM Hinton, FDA Chief Scientist, encouraged **early administration of remdesivir (COVID-19 viremic phase)** in the individual patient after COVID-19 laboratory confirmation in the asymptomatic state and forward.*

## Remdesivir for Adults With COVID-19

### A Living Systematic Review for an American College of Physicians Practice Points

Timothy J. Wilt, MD, MPH; Anjum S. Kaka, MD; Roderick MacDonald, MS; Nancy Greer, PhD; Adam Obley, MD;  
and Wei Duan-Porter, MD, PhD

**Background:** Few treatments exist for coronavirus disease 2019 (COVID-19).

**Purpose:** To evaluate the effectiveness and harms of remdesivir for COVID-19.

**Data Sources:** Several databases, tables of contents of journals, and U.S. Food and Drug Administration and company websites were searched from 1 January through 31 August 2020.

**Study Selection:** English-language, randomized trials of remdesivir treatments for adults with suspected or confirmed COVID-19. New evidence will be incorporated using living review methods.

**Data Extraction:** Single-reviewer abstraction and risk-of-bias assessment verified by a second reviewer; GRADE (Grading of Recommendations Assessment, Development and Evaluation) methods used for certainty-of-evidence assessments.

**Data Synthesis:** Four randomized trials were included. In adults with severe COVID-19, remdesivir compared with placebo probably improves recovery by a large amount (absolute risk difference [ARD] range, 7% to 10%) and may result in a small reduction in mortality (ARD range, -4% to 1%) and a shorter time to recovery or clinical improvement. Remdesivir may have little to no effect on hospital length of stay. Remdesivir probably reduces serious adverse events by a moderate amount (ARD range, -6% to -8%). Compared with a 10-day remdesivir course, a 5-day

course may reduce mortality, increase recovery or clinical improvement by small to moderate amounts, reduce time to recovery, and reduce serious adverse events among hospitalized patients not requiring mechanical ventilation. Recovery due to remdesivir may not vary by age, sex, symptom duration, or disease severity.

**Limitations:** Low-certainty evidence with few published trials, including 1 preliminary report and 2 open-label trials. Trials excluded pregnant women and adults with severe kidney or liver disease.

**Conclusion:** In hospitalized adults with COVID-19, remdesivir probably improves recovery and reduces serious adverse events and may reduce mortality and time to clinical improvement. For adults not receiving mechanical ventilation or extracorporeal membrane oxygenation, a 5-day course of remdesivir may provide similar benefits to and fewer harms than a 10-day course.

**Primary Funding Source:** U.S. Department of Veterans Affairs, Veterans Health Administration Office of Research and Development, Health Services Research and Development Service, and Evidence Synthesis Program.

Ann Intern Med. doi:10.7326/M20-5752

Annals.org

For author, article, and disclosure information, see end of text.  
This article was published at Annals.org on 5 October 2020.

## Inclusion Criteria

The following must be fulfilled in order to meet criteria for remdesivir

- ☐ Hospitalized with **SEVERE** COVID-19 (room air oxygen saturation < 94%, requiring supplemental oxygen or increase from baseline if on chronic oxygen therapy or is requiring invasive or non-invasive ventilation or ECMO)\*\*\*

- 608) 2020-10-05 McKenzie H: Could an intranasal COVID-19 vaccine be more efficient and effective than traditional approach? <https://www.biospace.com/article/why-an-intranasal-covid-19-vaccine-could-be-more-efficient-and-effective/>
- 609) 2020-10-06 Rogers TN: Meet the billionaire doctors behind Regeneron, the pharmaceutical company that developed Trump's experimental COVID-19 treatment. <https://www.businessinsider.com/regeneron-billionaires-schleifer-yancopoulos-trump-covid-drug-2020-10>
- 610) 2020-10-06 Jennings DG: Is Regeneron (NASDAQ: REGN) making money?—Market Mad House. <https://marketmadhouse.com/is-regeneron-nasdaq-regn-making-money/>

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**Treatment:** Passive Immunization: COVID-19 Convalescent Plasma and Antibodies and Antivirals  
**Prevention:** Active Immunization: Vaccines



- 611) 2020-10-07 Loftus P: Eli Lilly asks FDA to authorize Covid-19 antibody Drug. Wall Street Journal, Updated October 7, 2020, 11:31 pm ET. <https://www.wsj.com/articles/eli-lilly-asks-fda-to-authorize-covid-19-antibody-drug-11602074998>

If cleared for use, the drug could be the first to treat less severe cases of Covid-19. The few other therapies authorized for Covid-19 treatment, including remdesivir from [Gilead Sciences Inc.](#) [GILD 1.41%](#) and [convalescent plasma](#), target hospitalized patients with more serious cases.

Lilly said it would seek authorization for use in higher-risk patients to prevent their recently diagnosed mild-to-moderate disease from worsening to a severe state. Executives of the Indianapolis-based company said higher-risk groups may include people 65 years of age or older or obese patients.

“Anything that helps with preventing hospitalization and preventing progression is going to be a big advance,” Rajesh Tim Gandhi, an infectious-disease physician at Massachusetts General Hospital and Harvard Medical School, said in an interview.

Lilly’s antibody drug could also be the first in a new class of Covid-19 agents that not only might provide treatment but also potentially give temporary protection against the virus to people at risk of infection. That would [fill a gap until vaccines are authorized](#), though people may need to take the antibody drugs more than once to sustain the protection.

“When we started this project we always believed that vaccines would be a long-term solution but that antibodies could come to patients faster,” Lilly research head Daniel Skovronsky said in an interview. “We can make them faster, test them faster.”

The leading experimental antibody drugs have shown enough promise in testing so far that President Trump was [given one](#) developed by [Regeneron Pharmaceuticals Inc.](#) Regeneron said Wednesday night it has asked the Food and Drug Administration to authorize use of its antibody drug cocktail for Covid-19. The company said it has supply for 50,000 patients available and will have 300,000 within a few months.

Lilly said last month [its drug reduced the rate of hospitalization](#) compared with a placebo in a study. About 1.6% were hospitalized or visited the emergency room for Covid-19 after being injected with the drug, compared with 5.8% of people who didn’t get the drug in the study

- 612) 2020-10-07 Gumbrecht J, Howard J: Eli Lilly seeks EUA from FDA to Covid-19 antibody treatment. CNN Health. The 3 minute 42 second video attached to this article is the most succinct overview of antibody therapies that should be employed in the treatment of COVID-19 regarding both **Passive Immunization** [the early administration of exogenous neutralizing antibodies to individuals (<72 hours of COVID-19 detection or prophylactically)] and **Active Immunization** [vaccination of an individual which is prevention after the ~ 2-3 week increasing development of neutralizing antibodies in the uninfected individual). <https://www.cnn.com/2020/10/07/health/eli-lilly-antibody-therapy-results-eua/index.html>

- 613) 2020-10-08 Beigel JH, Tomashek KM, Dodd LE, Mehta AK, Zingman BS, Kalil A, Hohmann E, Chu HY, Luetkemeyer A, Kline S, Lopez de Castilla D, Finberg RW, Dierberg K, Tapson V, Hsieh L, Patterson TF, Paredes R, Sweeney DA, Short WR, Touloumi G, Lye

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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*  
**Prevention:** *Active Immunization:* Vaccines



DC, Ohmagari N, Oh Myoung-don, Ruiz-Palacios GM, Benfield T, Fatkenheuer G, Kortepeter MG, Atmar RL, Creech CB, Lundgren J, Babiker AG, Pett S, Neaton JD, Bergess TH, Bonnett T, Green M, Makowski M, Osinusi A, Nayak S, Lane HC, for the ACTT-1 Study Group Members. Remdesivir for the treatment of Covid-19 – Final Report. NEJM.org, October 8, 2020. Published in harcopy N Engl J Med 2020; 383:1813-1826. November 5, 2020. A preliminary version of this article was published on May 22, 2020. <https://www.nejm.org/doi/pdf/10.1056/NEJMoa2007764> .

## SAFETY OUTCOMES

In the as-treated population, serious adverse events occurred in 131 of 532 patients (24.6%) in the remdesivir group and in 163 of 516 patients (31.6%) in the placebo group (Table S17). There were 47 serious respiratory failure adverse events in the remdesivir group (8.8% of patients), including acute respiratory failure and the need for endotracheal intubation, and 80 in the placebo group (15.5% of patients) (Table S19). No deaths were considered by the investigators to be related to treatment assignment.

Grade 3 or 4 adverse events occurred on or before day 29 in 273 patients (51.3%) in the remdesivir group and in 295 (57.2%) in the placebo group (Table S18); 41 events were judged by the investigators to be related to remdesivir and 47 events to placebo (Table S17). The most common nonserious adverse events occurring in at least 5% of all patients included decreased glomerular filtration rate, decreased hemoglobin level, decreased lymphocyte count, respiratory failure, anemia, pyrexia, hyperglycemia, increased blood creatinine level, and increased blood glucose level (Table S20). The incidence of these adverse events was generally similar in the remdesivir and placebo groups.

Given the preliminary results about remdesivir, the Food and Drug Administration issued an Emergency Use Authorization on May 1, 2020 (modified on August 28, 2020), to permit the use of remdesivir for treatment in adults and children hospitalized with suspected or laboratory-confirmed Covid-19. Remdesivir has also received full or conditional approval in several other countries since that time. However, given high mortality despite the use of remdesivir, it is clear that treatment with an antiviral drug alone is not likely to be sufficient for all patients. Current strategies are evaluating remdesivir in combination with modifiers of the immune response (e.g., the Janus kinase [JAK] inhibitor baricitinib in ACTT-2, and interferon beta-1a in ACTT-3). A variety of therapeutic approaches including novel antivirals, modifiers of the immune response or other intrinsic pathways, and combination approaches are needed to continue to improve outcomes in patients with Covid-19.

**614)** 2020-10-08 Beaumont P, Boseley S, Glenza J: Provider of Trump Covid drug is president's golf friend. <https://www.theguardian.com/world/2020/oct/08/provider-of-trump-covid-drug-is-presidents-golf-friend>

**615)** 2020-10-08 Hart R: While Trump touts 'Cure' made by Regeneron, Its CEO is a member of Trump golf club. October 8, 2020. <https://www.forbes.com/sites/roberthart/2020/10/08/while-trump-touts-cure-made-by-regeneron-its-ceo-is-a-member-of-trump-golf-club/?sh=22fa6b7a60c8>

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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*  
**Prevention:** *Active Immunization:* Vaccines

- 616)** 2020-10-09 NIH—COVID-19 Treatment Guidelines – Coronavirus Disease 2019 (COVID-19) Treatment Guidelines, Convalescent Plasma. *Last Updated: October 9, 2020*, Page 102-108.  
<https://files.covid19treatmentguidelines.nih.gov/guidelines/archive/covid19treatmentguidelines-10-09-2020.pdf>

## Convalescent Plasma

*Last Updated: October 9, 2020*

Plasma from donors who have recovered from COVID-19 may contain antibodies to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) that may help suppress the virus and modify the inflammatory response.<sup>1</sup>

### Recommendation

- There are insufficient data for the COVID-19 Treatment Guidelines Panel (the Panel) to recommend either for or against the use of COVID-19 convalescent plasma for the treatment of COVID-19.

### Rationale for Recommendation

Currently, there are insufficient data from well-controlled, adequately powered, randomized clinical trials to evaluate the efficacy and safety of convalescent plasma for the treatment of COVID-19. However, >70,000 patients in the United States have received COVID-19 convalescent plasma through the Mayo Clinic's Expanded Access Program (EAP), which was designed primarily to provide broad access to investigational convalescent plasma and thus did not include an untreated control arm. Both the Food and Drug Administration (FDA) and the Mayo Clinic performed retrospective, indirect evaluations of efficacy by using the Mayo Clinic EAP data, hypothesizing that patients who received plasma units with higher titers of SARS-CoV-2 neutralizing antibodies would have better clinical outcomes than those who received plasma units with lower antibody titers. The results of their analyses suggest that convalescent plasma with high antibody titers may be more beneficial than low-titer plasma in nonintubated patients, particularly when administered within 72 hours of COVID-19 diagnosis.

The FDA determined that these findings—along with additional data from small randomized and nonrandomized studies, observational cohorts, and animal experiments—met the criteria for Emergency Use Authorization (EUA) issuance.<sup>2,3</sup> Despite meeting the “may be effective” criterion for EUA issuance, the EAP analyses are not sufficient to establish the efficacy or safety of convalescent plasma due to the lack of a randomized, untreated control group and potential confounding. There is no widely available and generally agreed-upon best test for measuring neutralizing antibodies, and the antibody titers of plasma from patients who have recovered from COVID-19 are highly variable. Furthermore, hospitalized patients with COVID-19 may already have SARS-CoV-2 neutralizing antibody titers that are comparable to those of plasma donors, potentially limiting the benefit of convalescent plasma in this patient population.<sup>4,5</sup> Several randomized, placebo-controlled trials of COVID-19 convalescent plasma are ongoing.

The Panel's assessment of the EAP data is consistent with the FDA statements in the convalescent plasma EUA documents.<sup>3,6,7</sup>

- 617)** 2020-10-09 Hancock J: As Trump touts his ‘great’ COVID drugs, the pharma cash flows to Biden, not him. <https://khn.org/news/trump-touts-covid-cure-regeneron-drug-pharma-political-contributions-strongly-benefit-biden/>
- 618)** 2020-10-10 BBC: White House hosted Covid ‘superspreader’ event, says Dr Fauci. <https://www.bbc.com/news/election-us-2020-54487154>

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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*  
**Prevention:** *Active Immunization:* Vaccines

- 619) 2020-10-10 Zimmermann P, Curtis N: Why is COVID-19 less severe in children? A review of the proposed mechanisms underlying the age-related difference in severity of SARS-CoV-2 infections. Arch Dis Children 2020;0:1-11.  
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- 620) 2020-10-11 Mack E: Regeneron CEO, a Dem Donor, rejects his treatment as ‘Cure’. Newsmax <https://www.newsmax.com/politics/regeneron-cure-treatment-covid/2020/10/11/id/991436/>
- 621) 2020-10-11 O’Brien C: Regeneron CEO: Trump ‘is a case of one’ and ‘weakness evidence’ for Covid-19 treatment. Politico  
<https://www.politico.com/news/2020/10/11/regeneron-trump-covid-coronavirus-428691>
- 622) 2020-10-11 Smith A: Trump declares himself ‘immune’ to Covid-19. His doctors won’t say when he last tested negative. NBC News. <https://www.nbcnews.com/politics/2020-election/trump-declares-himself-immune-covid-19-his-doctors-won-t-n1242851>
- 623) 2020-10-12 Tillett R, Sevinsky JR, Hartley PD, Kerwin H, Crawford N, Gorzalski A, Laverdure C, Verma SC, Rossetto CC, Jackson D, Farrell MJ, van Hooser S, Pandori M: Genomic evidence for reinfection with SARS-CoV-2: a case study. Lancet Infect Dis 2020; 21: 52-58. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7550103/pdf/main.pdf>
- 624) 2020-10-14 Eli Lilly and Company: Lilly statement on the NIAID decision to pause enrollment in ACTIV-3 clinical trial. <https://www.lilly.com/news/stories/statement-activ3-clinical-trial-covid19-niaid-decision-pause-enrollment>
- 625) 2020-10-14 Volkman E: Eli Lilly coronavirus antibody drug trial paused—The National Institutes of Health put the brakes on the study in what the drugmaker calls “an abundance of cautions.” The Motley Fool <https://www.fool.com/investing/2020/10/14/eli-lilly-coronavirus-antibody-drug-trial-paused/>
- 626) 2020-10-14 Buchanan L, Gamio L, Leatherby L, Keefe J, Koetti C, Schoenfeld Walker A: Tracking the White House Coronavirus Outbreak. The New York Times  
<https://www.nytimes.com/interactive/2020/10/02/us/politics/trump-contact-tracing-covid.html>
- 627) 2020-10-16 Hinton D, FDA Chief Scientist: U.S. Food & Drug Administration Emergency Use Authorization (EUA) regarding Remdesivir. Letter from RADM Hinton to Ms Rhoades, Gilead Sciences, Inc.  
<https://web.archive.org/web/20201017135559/https://www.fda.gov/media/137564/download>

Pages 1-2:

On May 1, 2020, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for emergency use of Veklury (remdesivir)<sup>3</sup> for the treatment of hospitalized patients with severe 2019 coronavirus disease (COVID-19)<sup>4</sup>, pursuant to Section 564 of the Act.

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**Treatment:** Passive Immunization: COVID-19 Convalescent Plasma and Antibodies and Antivirals  
**Prevention:** Active Immunization: Vaccines

Veklury is a direct acting antiviral drug that inhibits viral RNA synthesis. It is an investigational drug and is not currently approved for any indication.

On August 28, 2020, having concluded that revising this EUA is appropriate to protect the public health or safety under Section 564(g)(2) of the Act, FDA reissued the May 1, 2020, letter in its entirety with revisions incorporated to **expand the authorized use of Veklury by no longer limiting its use to the treatment of patients with severe disease.** In addition, the Fact Sheet for Health Care Providers was revised to provide updated clinical trial results and supporting data.<sup>5</sup>

**CONTRARY TO REFERENCE #4 WHICH STATES:** “For purposes of the May 1, 2020, EUA, patients with severe disease were defined as patients with oxygen saturation (SpO2) ≤94% on room air or requiring supplemental oxygen or requiring mechanical ventilation or requiring extracorporeal membrane oxygenation (ECMO).”, AS OF AUGUST 28, 2020, ...**“expand the authorized use of Veklury by no longer limiting its use to the treatment of patients with severe disease.”**

On October 1, 2020, having concluded that revising this EUA is appropriate to protect the public health or safety under Section 564(g)(2) of the Act, FDA reissued the August 28, 2020, letter in its entirety with revisions incorporated to the scope and conditions of authorization designating Gilead Sciences, Inc. and its authorized distributors<sup>6</sup> as the responsible parties for the distribution<sup>7</sup> of Veklury. FDA is reissuing the October 1, 2020, letter in its entirety with revisions to clarify that an alternate care site (ACS) meeting certain criteria is considered an “inpatient hospital setting” for the purposes of the scope of the EUA, and as such, is within the terms and conditions of FDA’s authorization.

Veklury has activity in cell culture and animal models against SARS-CoV, MERS-CoV, and SARS-CoV-2. Based on review of the data from the randomized, double-blinded, placebo-controlled trial conducted by NIAID (NCT04280705), from the Gilead-sponsored open-label trial that evaluated different durations of Veklury (NCT04292899), and from the Gilead-sponsored open-label trial that evaluated different durations of Veklury as compared to standard of care (NCT04292730), it is reasonable to believe that Veklury may be effective and the known and potential benefits of Veklury outweigh the known and potential risks of the drug for the treatment of patients hospitalized with COVID-19.

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of Veklury for treatment of COVID-19, as described in the Scope of Authorization section of this reissued letter (Section II) and subject to the terms of this authorization.

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<sup>1</sup> U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act*, 21 U.S.C. § 360bbb-3, February 4, 2020.

<sup>2</sup> U.S. Department of Health and Human Services, *Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act*, 21 U.S.C. § 360bbb-3, 85 FR 18250 (April 1, 2020).

<sup>3</sup> The May 1, 2020, EUA referred to the authorized drug as “remdesivir;” however, Gilead subsequently requested, and FDA concurred, that the Fact Sheets be altered to add references to remdesivir’s trade name, “Veklury.” “Veklury” is used in the August 28, 2020, reissued letter.

<sup>4</sup> For purposes of the May 1, 2020, EUA, patients with severe disease were defined as patients with oxygen saturation (SpO2) ≤94% on room air or requiring supplemental oxygen or requiring mechanical ventilation or requiring extracorporeal membrane oxygenation (ECMO). (PLEASE NOTE THAT AFTER AUGUST 28, 2020 THESE “SEVERITY OF DISEASE” WERE REVOKED BY THE FDA.)

<sup>5</sup> Prior to the reissuance of the EUA on August 28, 2020, and pursuant to the conditions of authorization, Gilead had requested, and FDA had concurred with, other changes to the Fact Sheets, including but not limited to: (1) clarified dosing and administration recommendations; (2) added sponsor's recommended formula to be used in calculating eGFR (this formula was removed in the August 28, 2020, reissuance); (3) added hypersensitivity reaction and drug interaction information; (4) added safety information from randomized clinical trials; (5) removed information related to the compassionate use program; and (6) added reference to remdesivir's trade name, Veklury.  
<sup>6</sup> "Authorized Distributor(s)" are identified by Gilead as an entity or entities allowed to distribute authorized Veklury.  
<sup>7</sup> Allocations of Veklury directed by the United States Government on or before September 30, 2020, remain valid and shall be distributed in collaboration with state or local government authorities, as needed.

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3. There is no adequate, approved, and available alternative to the emergency use of Veklury for the treatment of COVID-19. <sup>8</sup>

## II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited as follows:

- The Veklury covered by this authorization will be used only to treat adults and children with suspected or laboratory confirmed COVID-19 administered in an inpatient hospital setting<sup>9</sup> via intravenous (IV) infusion by a healthcare provider; and
- The use of Veklury covered by this authorization should be in accordance with the dosing regimens as detailed in the authorized Facts Sheets.

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<sup>8</sup> No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

<sup>9</sup> Individuals determined as being appropriate for acute inpatient hospitalization and who are admitted or transferred to an alternate care site (ACS) that is capable of providing acute care that is comparable to general inpatient hospital care are within the terms and conditions of this Letter of Authorization. An ACS is intended to provide additional hospital surge capacity and capability for communities overwhelmed by patients with COVID-19.

<sup>10</sup> The product labeled "investigational use" is authorized for use under this EUA; FDA is not requiring it to be relabeled given the immediate need for the product.

**628)** 2020-10-19 BBC News: England boosting plasma stocks for patients.  
<https://www.bbc.com/news/health-54597690>

**NHS Blood and Transplant is boosting stocks of blood plasma for very ill coronavirus patients ahead of winter.**

It wants more people who have recovered from Covid-19 to become donors.

Their **plasma contains antibodies that are believed to help other sufferers** fight the virus.

Fourteen new donation centres will open in November and December, to bring the total in England to 42. The blood plasma will be used to treat patients in Covid trials.

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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*  
**Prevention:** *Active Immunization:* Vaccines



**629)** 2020-10-20 KEI Staff: Regeneron failed to disclose BARDA funding in their REGN-COV2 patent. <https://www.keionline.org/34258>

**630)** 2020-10-21 Harris R: How will the limited supply of antibody drugs for COVID-19 be allocated? NPR October 21, 2020. <https://www.npr.org/sections/health-shots/2020/10/21/926376342/how-will-the-limited-supply-of-antibody-drugs-for-covid-19-be-allocated>

### 1. BARDA funds 80 percent of the R&D related to Regeneron's COVID-19 program

Regeneron has told their investors that the BARDA “is obligated to fund 80% of our costs incurred for certain research and development activities related to COVID-19 treatments.”<sup>1</sup> This commitment stems from the expansion of an existing contract with BARDA known as “HHSO100201700020C”.<sup>2</sup> Contract HHSO100201700020C was first established on September 29, 2017 to discover, research, develop, and manufacture antibody treatments against Ebola, Influenza, and other pathogens.<sup>3</sup> On January 31, 2020, BARDA and Regeneron expanded their collaboration under the HHSO100201700020C contract to include work relating to antibodies against COVID-19.<sup>4</sup>

According to BARDA, the base amount awarded to Regeneron under their collaboration specifically for work related to antibodies against COVID-19 was \$82,368,277.<sup>5</sup> Since then, Regeneron has further expanded their collaboration with the U.S. government. On July 7, 2020, the Department of Defense, through an intermediary called Advanced Technology International, awarded a \$450 million contract to Regeneron, to manufacture and supply REGN-COV2.<sup>6</sup> The extent to which costs are shared under the \$450 million contract is unknown.

As we explain in this report, the research leading to the selection of the two antibodies that comprise the REGN-COV2 cocktail was funded with the HHSO100201700020C contract.

**631)** 2020-10-22 Hinton DM, FDA Chief Scientist: U.S. Food & Drug Administration Emergency Use Authorization (EUA) regarding Remdesivir. Letter from RADM Hinton to Ms Rhoades, Gilead Sciences, Inc. <https://www.fda.gov/media/137564/download>

Pages 1-2:

On May 1, 2020, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for emergency use of Veklury® (remdesivir) for the treatment of hospitalized patients with severe 2019 coronavirus disease (COVID-19)<sup>3</sup>, pursuant to Section 564 of the Act. Veklury is a direct acting antiviral drug that inhibits viral RNA synthesis. At that time, Veklury was an investigational drug and not approved for any indication.

On August 28, 2020, having concluded that revising this EUA was appropriate to protect the public health or safety under Section 564(g)(2) of the Act, FDA reissued the May 1, 2020, letter in its entirety with revisions incorporated to **expand the authorized use of Veklury by no longer limiting its use to the treatment of patients with severe disease**. In addition, the Fact Sheet for Health Care Providers was revised to provide updated clinical trial results and supporting data.<sup>4</sup>

**CONTRARY TO THE EUA PRIOR TO AUGUST 28, 2020:** “For purposes of the May 1, 2020, EUA, patients with severe disease were defined as patients with oxygen saturation (SpO<sub>2</sub>) ≤94% on room air or requiring supplemental oxygen or requiring mechanical ventilation or requiring extracorporeal membrane

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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*  
**Prevention:** *Active Immunization:* Vaccines

oxygenation (ECMO).”, AS OF AUGUST 28, 2020, ...“**expand the authorized use of Veklury by no longer limiting its use to the treatment of patients with severe disease.**”

On October 1, 2020, having concluded that revising this EUA was appropriate to protect the public health or safety under Section 564(g)(2) of the Act, FDA reissued the August 28, 2020, letter in its entirety with revisions incorporated to the scope and conditions of authorization designating Gilead Sciences, Inc. and its authorized distributors<sup>5</sup> as the responsible parties for the distribution of Veklury. On October 16, 2020, FDA reissued the October 1, 2020, letter in its entirety with revisions to clarify that **an alternate care site (ACS) meeting certain criteria was considered an “inpatient hospital setting”** for the purposes of the scope of the EUA, and as such, was within the terms and conditions of FDA’s authorization. On October 22, 2020, FDA approved NDA 214787 for Veklury (remdesivir), which is indicated for adults and pediatric patients (12 years and older and weighing at least 40 kg) for the treatment of COVID-19 requiring hospitalization. Under its approval, **Veklury should only be administered in a hospital or in a healthcare setting capable of providing acute care comparable to inpatient hospital care.** Having concluded that revising this EUA is appropriate to protect the public health or safety under Section 564(g)(2) of the Act, FDA is reissuing the October 16, 2020, letter in its entirety with revisions to remove uses previously authorized that are now the subject of the approved NDA 214787 for Veklury, and to **continue authorizing Veklury for emergency use to treat suspected or laboratory-confirmed COVID-19 in hospitalized pediatric patients weighing 3.5 kg to less than 40 kg or hospitalized pediatric patients less than 12 years of age weighing at least 3.5 kg.**

Veklury has activity in cell culture and animal models against SARS-CoV, MERS-CoV, and SARS-CoV-2. Based on review of the data from the randomized, double-blinded, placebo controlled trial conducted by NIAID (NCT04280705), from the Gilead-sponsored open-label trial that evaluated different durations of Veklury (NCT04292899), and from the Gilead-sponsored open-label trial that evaluated different durations of Veklury as compared to standard of care (NCT04292730), it is reasonable to believe that Veklury may be effective and the known and potential benefits of Veklury outweigh the known and potential risks of the drug for the treatment of suspected or laboratory-confirmed COVID-19 in hospitalized pediatric patients weighing 3.5 kg to less than 40 kg or hospitalized pediatric patients less than 12 years of age weighing at least 3.5 kg.

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of Veklury for treatment of COVID-19, as described in the Scope of Authorization section of this reissued letter (Section II) and subject to the terms of this authorization

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<sup>1</sup> U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act*, 21 U.S.C. § 360bbb-3. February 4, 2020.

<sup>2</sup> U.S. Department of Health and Human Services, *Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act*, 21 U.S.C. § 360bbb-3, 85 FR 18250 (April 1, 2020).

<sup>3</sup> For purposes of the May 1, 2020, EUA, patients with severe disease were defined as patients with oxygen saturation (SpO<sub>2</sub>) ≤94% on room air or requiring supplemental oxygen or requiring mechanical ventilation or requiring extracorporeal membrane oxygenation (ECMO).

<sup>4</sup> Prior to the reissuance of the EUA on August 28, 2020, and pursuant to the conditions of authorization, Gilead had requested, and FDA had concurred with, other changes to the Fact Sheets, including but not limited to: (1) clarified dosing and administration recommendations; (2) added sponsor’s recommended formula to be used in calculating eGFR (this formula was removed in the August 28, 2020, reissuance); (3) added hypersensitivity reaction and drug interaction information; (4) added safety information from randomized, clinical trials; (5) removed information

related to the compassionate use program; and (6) added reference to remdesivir's trade name, Veklury.  
<sup>5</sup> "Authorized Distributor(s)" are identified by Gilead as an entity or entities allowed to distribute authorized Veklury.

**CONTRARY TO PRIOR TO AUGUST 28, 2020:** "For purposes of the May 1, 2020, EUA, patients with severe disease were defined as patients with oxygen saturation (SpO<sub>2</sub>) ≤94% on room air or requiring supplemental oxygen or requiring mechanical ventilation or requiring extracorporeal membrane oxygenation (ECMO).", AS OF AUGUST 28, 2020, ...**"expand the authorized use of Veklury by no longer limiting its use to the treatment of patients with severe disease."**

Page 3:

II. Scope of Authorization I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited as follows:

- The Veklury covered by this authorization will be used only to treat suspected or laboratory-confirmed COVID-19 in hospitalized<sup>7</sup> pediatric patients weighing 3.5 kg to less than 40 kg or hospitalized pediatric patients less than 12 years of age weighing at least 3.5 kg administered via intravenous (IV) infusion by a healthcare provider; and
- The use of Veklury covered by this authorization should be in accordance with the dosing regimens as detailed in the authorized Facts Sheets.

<sup>6</sup> No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

<sup>7</sup> Individuals determined as being appropriate for acute inpatient hospitalization and who are admitted or transferred to an alternate care site (ACS) that is capable of providing acute care that is comparable to general inpatient hospital care are within the terms and conditions of this Letter of Authorization. An ACS is intended to provide additional hospital surge capacity and capability for communities overwhelmed by patients with COVID-19.

<sup>8</sup> FDA's authorization includes remdesivir for injection manufactured and labeled prior to Gilead's reference to remdesivir's trade name, "Veklury", in product labeling.

**ALSO, PLEASE NOTE FOOTNOTE (7) ABOVE WHICH EXPANDS THE SITES OF INFUSION FROM "ACUTE INPATIENT HOSPITAL" TO "...ARE ADMITTED OR TRANSFERRED TO AN ALTERNATE CARE SITE (ACS) THAT IS CAPABLE OF PROVIDING ACUTE CARE THAT IS COMPARABLE TO GENERAL INPATIENT HOSPITAL CARE..."**

**632)** 2020-10-22: Farley JJ, Director, Office of Infectious Diseases, U.S. Food & Drug Administration: FDA New Drug Approval for Remdesivir **NDA 214787**. Letter from John Farley, MD, MPH to Ms Rhoades, Gilead Sciences, Inc. authorizing a **New Drug Authorization Approval**  
[https://www.accessdata.fda.gov/drugsatfda\\_docs/appletter/2020/214787Orig1s000ltr.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2020/214787Orig1s000ltr.pdf)

#### **NDA APPROVAL 214787**

Gilead Sciences, Inc.  
Attention: Ashley Rhoades, MBS, RAC  
Manager, Regulatory Affairs  
333 Lakeside Drive  
Foster City, CA 94404

Dear Ms. Rhoades:

----- September 18, 2023 -----  
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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*  
**Prevention:** *Active Immunization:* Vaccines

Please refer to your new drug application (NDA) dated and received August 7, 2020, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for VEKLURY (remdesivir) injection, 5 mg/mL; VEKLURY (remdesivir) for injection, 100 mg/vial.

This new drug application provides for the use of VEKLURY (remdesivir) injection, and VEKLURY (remdesivir) for injection, for adults and pediatric patients (12 years of age and older and weighing at least 40 kg) **for the treatment of coronavirus disease 2019 (COVID-19) requiring hospitalization. VEKLURY should only be administered in a hospital or in a healthcare setting capable of providing acute care comparable to inpatient hospital care.**

- 633) 2020-10-22 U.S. Food and Drug Administration: FDA News release. FDA approves first treatment for COVID-19. <https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-covid-19>

Today, the U.S. Food and Drug Administration approved the antiviral drug Veklury (remdesivir) for use in adult and pediatric patients 12 years of age and older and weighing at least 40 kilograms (about 88 pounds) for the treatment of COVID-19 requiring hospitalization. Veklury should only be administered in a hospital or in a healthcare setting capable of providing acute care comparable to inpatient hospital care. Veklury is the first treatment for COVID-19 to receive FDA approval.

This approval does not include the entire population that had been authorized to use Veklury under an Emergency Use Authorization (EUA) originally issued on May 1, 2020. In order to ensure continued access to the pediatric population previously covered under the EUA, the FDA revised the EUA for Veklury to authorize the drug's use for treatment of suspected or laboratory confirmed COVID-19 in hospitalized pediatric patients weighing 3.5 kg to less than 40 kg or hospitalized pediatric patients less than 12 years of age weighing at least 3.5 kg. Clinical trials assessing the safety and efficacy of Veklury in this pediatric patient population are ongoing.

**"The FDA is committed to expediting the development and availability of COVID-19 treatments during this unprecedented public health emergency,"** said FDA Commissioner Stephen M. Hahn, M.D. **"Today's approval is supported by data from multiple clinical trials that the agency has rigorously assessed and represents an important scientific milestone in the COVID-19 pandemic. As part of the FDA's Coronavirus Treatment Acceleration Program, the agency will to continue to help move new medical products to patients as soon as possible, while at the same time determining whether they are effective and if their benefits outweigh their risks."**

Under the Federal Food, Drug, and Cosmetic Act, approval of a new drug product requires substantial evidence of effectiveness and a demonstration of safety for the drug's intended use(s). In considering approval of a drug, the FDA conducts a benefit-risk assessment based on rigorous scientific standards to ensure that the product's benefits outweigh its risks for the intended population. This is different from the standard used in the issuance of an EUA.

The approval of Veklury was supported by the agency's analysis of data from three randomized, controlled clinical trials that included patients hospitalized with mild-to-severe COVID-19.

- 634) 2020-10-22 Gilead Sciences per FDA: Highlights of prescribing information for Veklury (Remdesivir) and FULL PRESCRIBING INFORMATION. [https://www.gilead.com/-/media/files/pdfs/medicines/covid-19/veklury/veklury\\_pi.pdf](https://www.gilead.com/-/media/files/pdfs/medicines/covid-19/veklury/veklury_pi.pdf)
- 635) 2020-10-22 U.S. Food and Drug Administration: Donate COVID-19 Plasma. <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/donate-covid-19-plasma>
- 636) 2020-10-23 Lerner S: Trump sets up pharma billionaires for coronavirus payday. Regeneron's federally funded Covid-19 treatment, which was used to treat Donald Trump, will likely be unavailable to most patients. The Intercept. *[As is stated in the yellow area below, "Regeneron...committed...to selling some of the antibodies to the government, which in turn is obligated to distribute them 'to the American people at no cost,'" according to the government's July 6 agreement, that deal applies to 'a fixed number of bulk lots.'"] That was a year ago. On April 13, 2021, it was announced that "Roche (was) taking the lead on development of the antibody cocktail outside of the U.S."*<sup>439</sup> *While REGN-COV2 is still an investigational biologic drug (monoclonal antibiotic cocktail) in the U.S. as of today, August 4, 2021, it is available to those who can obtain it in India for 59,000 Repees (~\$800 U.S.)*<sup>471</sup> <https://theintercept.com/2020/10/23/trump-covid-19-pharma-regeneron-coronavirus-treatment/>

### Shortages Expected

Hours after the president tweeted the video, in which he said that emergency use authorization for the antibody cocktail was "all set," Regeneron applied for the fast tracking, which would make the treatment available before it has been thoroughly vetted. But the Food and Drug Administration has yet to grant the authorization.

While Regeneron initially **estimated** that it would have between 70,000 and 300,000 doses "as early as end of summer and completed this fall," Schleifer **admitted** on CBS News' "Face the Nation" that, as of October 11, it had only produced 50,000 doses, which is fewer than the number of coronavirus infections diagnosed on a single day in the U.S. last week.

And although Regeneron has committed to selling some of the antibodies to the government, which in turn is obligated to distribute them "to the American people at no cost," according to the government's July 6 **agreement**, that deal applies only to "a fixed number of bulk lots." After that, the pricing is up to the company — a prospect that frightens some economists.

"Executives have an interest in getting the stock price up and price gouging customers is one way they can do this," said William Lazonick, professor emeritus of economics at University of Massachusetts and co-founder of the Academic-Industry Research Network. While many drug companies argue that they use their vast profits to fund ongoing pharmaceutical innovation, Lazonick said, "we've shown that most of these companies don't do that." Instead, the soaring prices fuel soaring stock prices and executive pay, which is often based largely on that price.

The **pharmaceutical industry** has a long history of opposing efforts to rein in drug prices, including the "affordable pricing" clause. Regeneron was fighting that measure, which obligates



companies that develop drugs with public money to sell them at reasonable prices, as far back as [1994](#).

Monoclonal antibodies are already among the most expensive pharmaceutical products available. The treatments on the market for conditions other than Covid-19 cost an average of \$96,731 per year. When used to treat cancer, the antibodies went for a median price of \$142,833, according to a 2018 [study](#) in the American Journal of Managed Care.

### A Looming Nightmare

While Trump promised that the government would provide the antibody cocktail to Americans for free, drug pricing efforts say that many people probably won't have access to the treatment at all, let alone at an affordable price.

"This is a looming nightmare," said Zain Rizvi, a drug pricing expert who works at Public Citizen. "If the drug is safe and effective, the shortages will be rampant and will exacerbate the insidious inequality that's already part of our healthcare system. The privileged few may get at the head of the line and the people who need it most may not have the same opportunities."

While Rizvi said that a lack of regulation plagues the entire U.S. pharmaceutical system, he said the maker of the antibody cocktail epitomizes the administration's failure to hold companies accountable during the pandemic. "The story of Regeneron's monoclonal antibody treatment is the story of president Trump's billionaire buddy who received massive taxpayer subsidies to work on a coronavirus treatment with no strings attached," said Rizvi, who pointed out that Regeneron will be able to both set high prices for the tax-payer funded treatment and market it exclusively. "You have massive public investment, but the knowledge that comes out of it is being privatized. It doesn't benefit public health."

Already the pandemic has showcased a brutal disparity in health care. Unlike Trump, who was given two cutting-edge treatments that are inaccessible to the general public a few days after being diagnosed, patients have often had to wait for medical care when hospitals were stretched to capacity — delays that sometimes proved deadly. Although the administration has set up a fund to help cover the costs of some coronavirus treatments, many patients [do not qualify](#). Some survivors of the disease have been hit with [staggering medical bills](#) for their treatments. And a lack of insurance is believed to have contributed to the astronomical toll of the pandemic, which has already claimed more than 223,000 lives.

For his part, Trump announced he was feeling "like perfect" after taking the Regeneron cocktail and hurried back to the White House. Once there, he helped fast-track the confirmation process of Amy Coney Barrett, his Supreme Court nominee who is widely expected to vote to strip tens of millions of Americans of their health care coverage and to outlaw the kind of research that produced the very treatment that he claims cured him.

Meanwhile, as the virus continues to surge across the country, Regeneron has said that it is continuing to produce its monoclonal antibodies and will do its best to make the treatment available to everyone.

"We are committed to ensuring that REGN-COV2 will be affordable for patients in need," Regeneron said in its emailed statement. "We know our medicines only help if people can access them, and, as such, we are working hard to develop and scale-up a completely novel treatment for COVID-19 that is accessible to the people who need it."

For Rizvi, the reassurance rings hollow. “The corporate executives will control the price and the supply,” he said. “What could go wrong?”

- 637) 2020-10-27 Regen Lab SA: Passive immune prophylaxis preventing COVID-19 with ‘Acellular-Convalescent Plasma’ (A-CP): a new technology introduced by Regen Lab®. <https://www.prnewswire.com/in/news-releases/passive-immune-prophylaxis-preventing-covid-19-with-acellular-convalescent-plasma-a-cp-a-new-technology-introduced-by-regen-lab-r--807452422.html>
- 638) 2020-10-27 Yeager A: Eli Lilly halts antibody trial in hospitalized COVID-19 patients. Recent data show that the drug bamlanivimab, also known as LY-CoV555, does not appear to help those with severe cases of COVID-19, but trials continue for milder cases. TheScientist <https://www.the-scientist.com/news-opinion/eli-lilly-halts-antibody-trial-in-hospitalized-covid-19-patients-68090>
- 639) 2020-10-28 Chen P, Nirula A, Heller B, Gottlieb RL, Boscia J, Morris J, Huhn G, Cardona J, Mocherla B, Stosor V, Shawa I, Adams AC, Naarden J, Custer KL, Shen L, Durante M, Oakley G, Schade AE, Sabo J, Patel DR, Klekotka P, Skovronsky DM, for the BLAZER-1 Investigators. SARS-CoV-2 neutralizing antibody LY-CoV555 in outpatients with Covid-19. NEJM.org October 28, 2020; published in N Engl J Med, January 21, 2021; 384 (3): 229-237. <https://www.nejm.org/doi/pdf/10.1056/NEJMoa2029849?articleTools=true>
- 640) 2020-10-28 Regeneron: Regeneron’s COVID-19 outpatient trial prospectively demonstrates that REGN-COV2 antibody cocktail significantly reduced virus levels and need for further medical attention. <https://investor.regeneron.com/news-releases/news-release-details/regenerons-covid-19-outpatient-trial-prospectively-demonstrates>

## REGENERON'S COVID-19 OUTPATIENT TRIAL PROSPECTIVELY DEMONSTRATES THAT REGN-COV2 ANTIBODY COCKTAIL SIGNIFICANTLY REDUCED VIRUS LEVELS AND NEED FOR FURTHER MEDICAL ATTENTION

TARRYTOWN, N.Y., Oct. 28, 2020 /PRNewswire/ --

**Today's data, involving an additional 524 patients from the ongoing Phase 2/3 trial, provides definitive final virology results and meets the clinical endpoint of reducing medical visits**

**Regeneron has shared these results with the U.S. FDA, which is reviewing an Emergency Use Authorization submission for the REGN-COV2 low dose in adults with mild-to-moderate COVID-19 who are at high risk for poor outcomes**

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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*  
**Prevention:** *Active Immunization:* Vaccines

Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) today announced positive, prospective results from **an ongoing Phase 2/3 seamless trial** in the COVID-19 outpatient setting showing its investigational antibody cocktail, REGN-COV2, met the primary and key secondary endpoints. REGN-COV2 significantly reduced viral load and patient medical visits (hospitalizations, emergency room, urgent care visits and/or physician office/telemedicine visits).

"The first job of an antiviral therapeutic drug is to lower the viral load, and our initial data in 275 patients strongly suggested that the REGN-COV2 antibody cocktail could lower viral load and thereby potentially improve clinical outcomes. Today's analysis, involving more than 500 additional patients, prospectively confirms that REGN-COV2 can indeed significantly reduce viral load and further shows that these viral reductions are associated with a significant decrease in the need for further medical attention," said George D. Yancopoulos, M.D., Ph.D., President and Chief Scientific Officer of Regeneron. "We continue to see the strongest effects in patients who are most at risk for poor outcomes due to high viral load, ineffective antibody immune response at baseline, or pre-existing risk factors. Regeneron has shared these results with the U.S. Food and Drug Administration as part of its review of our Emergency Use Authorization submission, and we continue to focus on completing our ongoing trials evaluating REGN-COV2 for the treatment and prevention of COVID-19."

The randomized, double-blind trial is measuring the effect of adding REGN-COV2 to usual standard-of-care, compared to adding placebo to standard-of-care. A descriptive analysis from the first 275 patients was [previously reported](#). Today's data, involving an additional 524 patients, show the trial met all of the first nine endpoints in the statistical hierarchy, which assessed virologic endpoints based on viral load, seronegative status and dose group, as well as the key clinical endpoint of COVID-19 related medically-attended visits, in patients who had laboratory-confirmed COVID-19 at baseline. Results showed no significant difference in virologic or clinical efficacy between the REGN-COV2 high dose (8 grams) and low dose (2.4 grams). Based on this finding, Regeneron is reviewing potential changes to dosing in the ongoing outpatient clinical trial given the current limited supply of REGN-COV2.

**Virologic results (n=524, prospectively confirming previous 275-patient analysis):**

- 641)** 2020-10-28 Lilly: Lilly announces agreement with U.S. government to supply 300,000 vials of investigational neutralizing antibody bamlanivimab (LY-CoV555) in an effort to fight COVID-19. <https://investor.lilly.com/node/43881/pdf>

Lilly has successfully completed a Phase 1 study of bamlanivimab in hospitalized patients with COVID-19 (<https://clinicaltrials.gov/ct2/show/NCT04411628>). A Phase 2 study in people recently diagnosed with COVID-19 in the ambulatory setting (BLAZE-1, <https://clinicaltrials.gov/ct2/show/NCT04427501>) is ongoing. A Phase 3 study of bamlanivimab for the prevention of COVID-19 in residents and staff at long-term care facilities (BLAZE-2, <https://clinicaltrials.gov/ct2/show/NCT04497987>) is also ongoing. In addition, bamlanivimab is being tested in the National Institutes of Health-led ACTIV-2 study of ambulatory COVID-19 patients.

Eli Lilly and company have twelve Clinical Trials posted as of June 1, 2021 on NIH <https://clinicaltrials.gov> and only one is listed as a Phase I trial (which was nominally completed

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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*  
**Prevention:** *Active Immunization:* Vaccines

on August 26, 2020). Therefore, as of August 26, 2020, Eli Lilly's monoclonal antibody (Ly-CoV555) bamlanivimab <https://clinicaltrials.gov/ct2/show/NCT04411628?term=eli+lilly&cond=Covid19&draw=2&rank=4> met the criteria of the intent of PL-115-176, the Right to Try Act of 2017, which stipulates that the only requirement that must be met so that a patient can request an Investigational Drug or Biologic outside of a clinical trial is that a **Phase I clinical trial be "completed."** The nominal completion date of NCT04411628 on NIH <https://clinicaltrials.gov> is **August 26, 2020**. While the monoclonal antibody bamlanivimab met the criteria set forth by the FDA <https://www.fda.gov/media/72057/download> and by the NIH <https://grants.nih.gov/grants/guide/notice-files/not-od-16-149.html> for a completed **Phase I Clinical Trial**, the FDA, the NIH, and Eli Lilly failed to notify the American public, the American Medical profession, and the rest of the Federal Government that bamlanivimab should have been available to all Americans within 72 hours of documented contraction of COVID-19 from August 26, 2020 to the present at their request under PL-155-176, the Right to Try Law, <https://www.govinfo.gov/content/pkg/PLAW-115publ176/pdf/PLAW-115publ176.pdf>.

**642)** 2020-10-30 McGrail S: Eli Lilly strikes deal with Govt over COVID-19 antibody drug. HHS and DoD will purchase the first doses of the COVID-19 antibody as part of Operation Warp Speed's goals to deliver coronavirus treatments to patients by the end of 2020. PHARMANEWS INTELLIGENCE <https://pharmanewsintel.com/news/eli-lilly-strikes-deal-with-govt-over-covid-19-antibody-drug>

**643)** 2020-10-30 Regeneron: REGN-COV2 independent data monitoring committee recommends holding enrollment in hospitalized patients with high oxygen requirements and continuing enrollment in patients with low or no oxygen requirements. <https://investor.regeneron.com/news-releases/news-release-details/regn-cov2-independent-data-monitoring-committee-recommends> *Please note, this announcement confirms that antibody therapy should be administered early (<72 hours) in the clinical course of all individual COVID-19 positive patients.*

**644)** 2020-10-30 McGrail S: Eli Lilly strikes deal with Govt over COVID-19 antibody drug. PHARMANEWS INTELLIGENCE xtelligent HEALTHCARE MEDIA. <https://pharmanewsintel.com/news/eli-lilly-strikes-deal-with-govt-over-covid-19-antibody-drug>

**645)** 2020-11 Simoneaux R, Shafer SL: A RAS and Bradykinin-mediated mechanism for COVID-19. ASA Monitor 2020 November; 84: 1-11. <https://pubs.asahq.org/monitor/article/84/11/1/110833/A-RAS-and-Bradykinin-Mediated-Mechanism-for-COVID>

**646)** 2020-11 Liu STH, Lin HM, Biane I, Wajnberg A, Gumprecht JP, Rahman F, Rodriguez D, Tandon P, Bassily-Marcus A Bander J, Sanky C, Dupper A, Zheng A, Nguyen FT, Amanat F, Stadlbauer D, Altman DR, Chen BK, Krammer F, Mendu DR, Firpo-Betancourt A, Levin MA, Bagiella E, Casadevall A, Cordon-Cardo C, Jhang JS, Arinsburg SA, Reich DL, Aberg JA, Bouvier NM: Convalescent plasma treatment of severe COVID-19: a propensity score-matched control study. Nature Medicine 2020 November; 26: 1708-1713. <https://www.nature.com/articles/s41591-020-1088-9>

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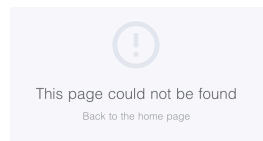
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**Prevention:** Active Immunization: Vaccines

...This retrospective, propensity score-matched case-control study assessed the effectiveness of convalescent plasma therapy in 39 patients with severe or life-threatening COVID-19 at the Mount Sinai Hospital in New York City. Oxygen requirements on day 14 after transfusion worsened in 17.9% of plasma recipients versus 28.2% of propensity score-matched controls who were hospitalized with COVID-19 (adjusted odds ratio (OR), 0.86; 95% confidence interval (CI), 0.75-0.98; chi-square test P value=0.025. Survival also improved in plasma recipients (adjusted hazard ratio (HR), 0.34; 95% CI, 0.13-0.89; chi-square test P value=0.027). Convalescent plasma is potentially effective against COVID-19, but adequately powered, randomized controlled trials are needed.

- 647) 2020-11-01 Echevarria K: Remdesivir (VEKLURY) Criteria for use November 2020. U.S. Department of Veterans Affairs, Veteran Health Administration, VA Pharmacy Benefits Management Services 10P4P.  
[https://vanf.app/CFU\\_PDF/Remdesivir\\_VEKLURY\\_November2020.pdf](https://vanf.app/CFU_PDF/Remdesivir_VEKLURY_November2020.pdf)

In my preparation of my dutiful submission in January 2022, when I attempted to access the URL above on January 5, 2022, the following came up:



When one clicks on: “Back to the home page” <https://vanf.app/> :

This is flagrant electronic destruction of official U.S. government documentation by a Service of an Agency of the Executive Branch of the U.S. Federal Government: VA Pharmacy Benefits Management Services 10PAP, Veterans Health Administration, U.S. Department of Veterans Affairs, which is overseen by Carolyn Clancy, M.D., M.A.C.P., VHA Deputy Under Secretary for Health (DUSH) for Discovery, Education & Affiliated Networks (DEAN). Below is the document that has been removed from the Internet that contains erroneous information in the “**Inclusion Criteria.**”

When one clicks on: “Back to the home page” <https://vanf.app/> :

This is flagrant electronic destruction of official U.S. government documentation by a Service of an Agency of the Executive Branch of the U.S. Federal Government: VA Pharmacy Benefits Management Services 10PAP, Veterans Health Administration, U.S. Department of Veterans Affairs, which is overseen by Carolyn Clancy, M.D., M.A.C.P., VHA Deputy Under Secretary for Health (DUSH) for Discovery, Education & Affiliated Networks (DEAN).

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**Prevention:** *Active Immunization:* Vaccines



Below is the document that has been removed by the VA from the Internet that contains erroneous information in the “**Inclusion Criteria.**” THE DOCUMENT BELOW FROM THE VA Pharmacy Benefits Management Services remained under the URL above for several months! Even using the Wayback Machine, *Remdesivir (VEKLURY) Criteria for Use November 2020* cannot be found today! --Charles Andrus, M.D., F.A.C.S. 5/14/2022

The screenshot shows the VA Formulary Advisor website. At the top is a navigation bar with a search bar containing 'vanf.app' and several utility icons. Below this is a dark blue header with the site name 'VA Formulary Advisor' on the left and links for 'Home', 'Glossary', 'About', and 'Feedback' on the right. The main content area has a light blue background. On the left, there's a sidebar with a search bar and filter buttons for 'Drug', 'Drug Class', and 'Therapeutic Category'. Below the search bar is a text input field with the placeholder 'Enter at least three characters'. Further down are three filter buttons: 'VA Formulary', 'Urgent/Emergent Formulary', and 'All'. The right side of the page contains introductory text about the resource, its goal, and instructions on how to use the search function.

Remdesivir (Veklury) CEU

Remdesivir (VEKLURY) CEU

## Remdesivir (VEKLURY) Criteria for Use November 2020

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, and is not intended to be used as a standard or to impose the quality of patient care, and to promote an effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information

See the VA National PBM-MAP-VPE Monograph on this drug at [www.pbm.va.gov](http://www.pbm.va.gov) or <http://vawww.pbm.va.gov> for further information.

### Exclusion Criteria

**Exclusion Criteria**

If the answer to ANY item below is met, then the patient should NOT receive remdesivir

- ☐ Treated for COVID-19 as an outpatient
- ☐ AST or ALT > 5 times the upper limit of normal
- ☐ Hospitalized patients but NOT requiring supplemental oxygen\*
- ☐ Concomitant use of hydroxychloroquine or chloroquine
- ☐ Current eGFR < 30 mL/min\*\*

### Inclusion Criteria

The following must be fulfilled in order to meet criteria for remdesivir

- ☐ Hospitalized with **SEVERE** COVID-19 (room air oxygen saturation < 94%, requiring supplemental oxygen or increase from baseline if on chronic oxygen therapy or is requiring invasive or non-invasive ventilation or ECMO)\*\*\*

### Supplemental Information

Recommended initial duration of therapy is 5 days, with the potential to extend to 10 days in patients who are not improving or who remain critically ill. Therapy can be discontinued when the patient is appropriate for discharge, even if the full duration of therapy has not been given.

*\*Use in hospitalized patients with mild to moderate COVID-19 at high risk for progression to severe disease may be appropriate and should be adjudicated on a case by case basis*

**\*\*Patients with eGFR < 30 mL/min (or CrCl < 30-50 mL/min depending on the trial) were excluded from clinical trials and routine use is not recommended by the manufacturer. Use may be considered and adjudicated on a case by case basis if the benefit is felt to outweigh the risks, especially when renal function is likely to improve rapidly (e.g. dehydration). The mechanism of calculating renal function can be based on local guidance.**

\*\*\*Remdesivir alone is not recommended alone for patients on mechanical ventilation or ECMO but may be considered in conjunction with corticosteroids in patients who have recently been intubated, according to the NIH Treatment Guidelines for COVID-19

Prepared: November 2020. Contact: Kelly Echevarria, PharmD, BCPS, AQ-ID, BCIDP, National Clinical Pharmacy Program Manager. VA Pharmacy Benefits Management Services 10P4P

Updated version may be found at [PBM INTERNet](#) or [PBM INTRANet](#)

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**Prevention:** *Active Immunization:* Vaccines

648) 2020-11-03 Epstein J, Smid WM, Wendel S, Somuah D, Burnouf T: Plasma-Based COVID-19 treatments in low-and middle- income countries and the risk of transfusion-transmitted infections. Npj | Vaccines, [www.nature.com/npjvaccines](https://www.nature.com/npjvaccines)  
<https://www.nature.com/articles/s41541-020-00256-6.pdf> From 1995 to 2017, Dr. Epstein was the Director, Office of Blood Research and Review, CBER, FDA.  
[https://www.who.int/biologicals/expert\\_committee/BIO\\_EPSTEIN\\_Jay\\_2018.pdf](https://www.who.int/biologicals/expert_committee/BIO_EPSTEIN_Jay_2018.pdf)

649) 2020-11-05 Aljazeera: Regeneron hopes US will greenlight COVID-19 antibody drug soon. <https://www.aljazeera.com/economy/2020/11/5/regeneron-hopes-us-will-green-light-covid-19-antibody-drug-soon>

Regeneron Pharmaceuticals Inc said United States health regulators were doing a careful analysis of its experimental antibody cocktail to treat COVID-19 and that it was hopeful the drug could be authorized for emergency use in the country soon. ...

...Based on clinical trials, Regeneron expects emergency use authorisation could be granted for outpatients, a group that it believes would benefit the most from the drug.

About 80,000 doses of the treatment could be ready by the end of this month, and 300,000 doses by the end of January, Regeneron said.

650) 2020-11-05 Beigel JH, Tomasek KM, Dodd LE, Mehta AK, Zingman BS, Kalil AC, Hohmann E, Chu HY, Luetkemeyer A, Kline S, Lopez de Castilla D, Finberg RW, Dierberg K, Tapson V, Hsieh L, Patterson TF, Paredes R, Sweeney DA, Short WR, Touloumi G, Lye DC, Oh M, Ruiz-Palacios GM, Benfield T, Fatkenheuer G, Kortepeter MG, Atmar RL, Creech CB, Lundgren J, Babiker AG, Pett S, Neaton JD, Burgess TH, Bonnett T, Green M, Makowski M, Osinusi A, Nayak S, and Lane HC for the ACTT-1 Study Group Members. Remdesivir for the Treatment of Covid-19 – Final Report. N Engl J Med 2020 Nov 5; 383 (19); 1813-1826. <https://www.nejm.org/doi/pdf/10.1056/NEJMoa2007764?articleTools=true>

**(ABSTRACT) CONCLUSIONS** Our data show that remdesivir was superior to placebo in shortening the time to recovery in adults who were hospitalized with Covid-19 and had evidence of lower respiratory tract infection. (Funded by the National Institute of Allergy and Infectious Diseases and others; ACTT-1 ClinicalTrials.gov number, NCT04280705.) **PLEASE NOTE THAT THIS STUDY WAS FUNDED “PRIMARILY” BY THE NIAID OF WHICH Dr. Fauci is the Director. FROM NOVEMBER 5, 2020, TO THE PRESENT EVERY MAN, WOMAN, AND CHILD WHO CONTRACTED COVID-19 SHOULD HAVE BEEN OFFERED REMDESIVIR AS SOON AS THEY TESTED POSITIVE.**

Page 1814: ...Remdesivir (GS-5734), an inhibitor of the viral RNA-dependent, RNA polymerase with in vitro inhibitory activity against SARS-CoV-1 and the Middle East respiratory syndrome (MERS-CoV),<sup>5-8</sup> was identified early as a promising therapeutic candidate for Covid-19 because of its ability to inhibit SARS-CoV-2 in vitro.<sup>9</sup> In addition, in nonhuman primate studies,

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**Prevention:** Active Immunization: Vaccines

remdesivir initiated 12 hours after inoculation with MERS-CoV10,11 reduced lung virus levels and lung damage.

To evaluate the clinical efficacy and safety of putative investigational therapeutic agents among hospitalized adults with laboratory-confirmed Covid-19, we designed an adaptive platform trial to rapidly conduct a series of phase 3, randomized, double-blind, placebo-controlled trials. Here, we describe the first stage of the Adaptive Covid-19 Treatment Trial (ACTT-1), in which we evaluated treatment with remdesivir as compared with placebo. The results presented here represent an update to a preliminary report after complete follow-up.

Page 1825: ...Given the preliminary results about remdesivir, the Food and Drug Administration issued an Emergency Use Authorization on May 1, 2020 (modified on August 28, 2020), to permit the use of remdesivir for treatment in adults and children hospitalized with suspected or laboratory-confirmed Covid-19. Remdesivir has also received full or conditional approval in several other countries since that time. However, given high mortality despite the use of remdesivir, it is clear that treatment with an antiviral drug alone is not likely to be sufficient for all patients.

Page 1825: ...The trial was sponsored and primarily funded by the NIAID, National Institutes of Health (NIH), Bethesda, MD. This trial has been funded in part with federal funds from the NIAID and the National Cancer Institute, NIH, under contract HHSN261200800001E 75N910D00024, task order number 75N91019F00130/75N91020F00010, and by the Department of Defense, Defense Health Program. This trial has been supported in part by the NIAID of the NIH under award numbers UM1AI148684, UM1AI148576, UM1AI148573, UM1AI148575, UM1AI148452, UM1AI148685, UM1AI148450, and UM1AI148689. The trial has also been funded in part by the governments of Denmark, Japan, Mexico, and Singapore. The trial site in South Korea received funding from the Seoul National University Hospital. Support for the London International Coordinating Centre was also provided by the United Kingdom Medical Research Council (MRC \_UU\_12023/23).

- 651) 2020-11-06 Lupkin S: Federal supply deal for COVID-19 antibody treatment lacks some customary protections. NPR. <https://www.npr.org/sections/health-shots/2020/11/06/931795256/federal-supply-deal-for-covid-19-antibody-treatment-lacks-some-customary-protect>
- 652) 2020-11-08 Tenny S, Varacallo M: Evidence Based Medicine. Treasure Island, FL: StatPearls Publishing, 2021 Jan <https://www.ncbi.nlm.nih.gov/books/NBK470182/>
- 653) 2020-11-09 Hinton DM: Emergency Use Authorization regarding Eli Lilly's bamlanivimab. U.S. Food & drug, November 10, 2021. <http://web.archive.org/web/20201109232745/https://www.fda.gov/media/143602/download>
- 654) 2020-11-09 Food and Drug Administration: Coronavirus (COVID-19) update: FDA authorizes monoclonal antibody for treatment of COVID-19. FDA news release, November 9, 2020. <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-monoclonal-antibody-treatment-covid-19>
- 655) 2020-11-09 Centers for Medicare and Medicaid: Medicare monoclonal antibody COVID-19 infusion program instruction. First issued about November 12, 2020 but is not dated so this is the present version in May 2021.

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<https://www.cms.gov/files/document/covid-medicare-monoclonal-antibody-infusion-program-instruction.pdf> The present version gives the history of these instructions and provides for any physician to be able administer these to patients under the EUAs:

On November 9, 2020, the U.S. Food and Drug Administration (FDA) issued an emergency use authorization (EUA) for the investigational monoclonal antibody therapy, bamlanivimab, for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients with positive COVID-19 test results who are at high risk for progressing to severe COVID-19 and/or hospitalization. Bamlanivimab may only be administered in settings in which health care providers have immediate access to medications to treat a severe infusion reaction, such as anaphylaxis, and the ability to activate the emergency medical system (EMS), as necessary. Review the Fact Sheet for Health Care Providers EUA of Bamlanivimab regarding the limitations of authorized use.

On November 21, 2020, the FDA issued an EUA for the investigational monoclonal antibody therapy, casirivimab and imdevimab, administered together, for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients with positive COVID-19 test results who are at high risk for progressing to severe COVID-19 and/or hospitalization. As with the other monoclonal antibody infusion treatments, casirivimab and imdevimab may only be administered in settings in which health care providers have immediate access to medications to treat a severe infusion reaction, such as anaphylaxis, and the ability to activate the emergency medical system (EMS), as necessary. Review the Fact Sheet for Health Care Providers EUA of Casirivimab and Imdevimab regarding the limitations of authorized use when administered together.

On February 9, 2021, the FDA issued an EUA for the investigational monoclonal antibody therapy, bamlanivimab and etesevimab, administered together, for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients with positive COVID-19 test results who are at high risk for progressing to severe COVID-19 and/or hospitalization. As with the other monoclonal antibody infusion treatments, bamlanivimab and etesevimab may only be administered in settings in which health care providers have immediate access to medications to treat a severe infusion reaction, such as anaphylaxis, and the ability to activate the emergency medical system (EMS), as necessary. Review the Fact Sheet for Health Care Providers EUA of Bamlanivimab and Etesevimab regarding the limitations of authorized use when administered together.

During the COVID-19 public health emergency (PHE), Medicare will cover and pay for these infusions (when furnished consistent with their respective EUAs) the same way it covers and pays for COVID-19 vaccines.

This would allow a broad range of providers and suppliers, including freestanding and hospital-based infusion centers, home health agencies, nursing homes, and entities with whom nursing homes contract for this, to administer these treatments in accordance with the EUA. Medicare will not pay for the COVID-19 monoclonal antibody products that providers receive for free. If providers begin to purchase COVID-19 monoclonal antibody products, Medicare anticipates setting the payment rate for the products, which will be 95% of the average wholesale price (AWP) for many health care providers, consistent with usual vaccine payment methodologies. Additionally, Medicare anticipates establishing codes and rates for the administration of the products.

In order to facilitate the efficient administration of COVID-19 vaccines to SNF residents, CMS will exercise enforcement discretion with respect to certain statutory provisions as well as any associated statutory references and implementing regulations, including as interpreted in pertinent guidance (collectively, "SNF Consolidated Billing Provisions"). Through the exercise of that discretion, CMS will allow Medicare-enrolled immunizers including, but not limited to,

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pharmacies working with the United States, as well as infusion centers, and home health agencies to bill directly and receive direct reimbursement from the Medicare program for vaccinating Medicare SNF residents.

Health care providers administering the COVID-19 monoclonal antibody infusions will follow the same enrollment process as those administering the other COVID-19 vaccines. Review provider enrollment information. <https://www.cms.gov/medicare/covid-19/enrollment-administering-covid-19-vaccines>

**656)** 2020-11-09 Lilly INVESTORS: Lilly's neutralizing antibody bamlanivimab (LY-CoV555) receives FDA emergency use authorization for the treatment of recently diagnosed COVID-19. <https://investor.lilly.com/news-releases/news-release-details/lillys-neutralizing-antibody-bamlanivimab-ly-cov555-receives-fda>

**657)** 2020-11-09 Lee SM: The FDA has authorized the COVID-19 antibody drug that Christie took—Eli Lilly's experimental coronavirus therapy, bamlanivimab, received an emergency use authorization for mild to moderate COVID-19. BuzzFeed News <https://www.buzzfeednews.com/article/stephaniemlee/fda-coronavirus-antibody-therapy-eli-lilly>

**658)** 2020-11-10 Hinton DM: Emergency Use Authorization regarding Eli Lilly's bamlanivimab. U.S. Food & drug, November 10, 2021. <http://web.archive.org/web/20210123043558/https://www.fda.gov/media/143602/download>

**659)** 2020-11-10 Centers for Medicare and Medicaid: CMS takes steps to ensure medicare beneficiaries have wide access to COVID-19 antibody treatment. <https://www.cms.gov/newsroom/press-releases/cms-takes-steps-ensure-medicare-beneficiaries-have-wide-access-covid-19-antibody-treatment> This is printed *verbatim*:

**Updated: November 13, 2020**

The Centers for Medicare & Medicaid Services announced that starting today, Medicare beneficiaries can receive coverage of monoclonal antibodies to treat coronavirus disease 2019 (COVID-19) with no cost-sharing during the public health emergency (PHE). CMS' coverage of monoclonal antibody infusions applies to bamlanivimab, which received an emergency use authorization (EUA) from the U.S. Food and Drug Administration yesterday.

"Today, CMS is announcing a historic, first-of-its kind policy that drastically expands access to COVID-19 monoclonal antibodies to beneficiaries without cost sharing," said CMS Administrator Seema Verma. "Our timely approach means beneficiaries can receive these potentially life-saving therapies in a range of settings – such as in a doctor's office, nursing home, infusion centers, as long as safety precautions can be met. This aggressive action and innovative approach will undoubtedly save lives."

CMS anticipates that this monoclonal antibody product will initially be given to health care providers at no charge. Medicare will not pay for the monoclonal antibody products that providers receive for free but today's action provides for reimbursement for the infusion of the

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product. When health care providers begin to purchase monoclonal antibody products, Medicare anticipates setting the payment rate in the same way it set the payment rates for COVID-19 vaccines, such as based on 95% of the average wholesale price for COVID-19 vaccines in many provider settings. This means that cases that include the use of monoclonal antibody COVID-19 products will not be eligible for the enhanced payment established under the Medicare Inpatient Prospective Payment System (IPPS) in CMS-9912-IFC. CMS will issue billing and coding instructions for health care providers in the coming days.

CMS anticipates the announcement today will allow for a broad range of providers and suppliers, including freestanding and hospital-based infusion centers, home health agencies, nursing homes, and entities with whom nursing homes contract, to administer this treatment in accordance with the EUA, and bill Medicare to administer these infusions.

Under section 6008 of the Families First Coronavirus Response Act (FFCRA), state and territorial Medicaid programs may receive a temporary 6.2 percentage point increase in the Federal Medical Assistance Percentage (FMAP), through the end of the quarter in which the COVID-19 PHE ends. A condition for receipt of this enhanced federal match is that a state or territory must cover COVID-19 testing services and treatments, including vaccines and their administration, specialized equipment, and therapies for Medicaid enrollees without cost sharing. This means that this monoclonal antibody infusion is expected to be covered when furnished to Medicaid beneficiaries, in accordance with the EUA, during this period, with limited exceptions.

To view the Monoclonal Antibody COVID-19 Infusion Program Instruction, visit:

<https://www.cms.gov/files/document/covid-medicare-monoclonal-antibody-infusion-program-instruction.pdf>

- 660)** 2020-11-10 Skovronsky D: When the World called for help with COVID-19, We were ready. <https://www.lilly.com/news/stories/daniel-skovronsky-covid19-scientific-discovery-innovation>
- 661)** 2020-11-10 HHS.gov: HHS allocates Lilly therapeutic to treat patients with mild to moderate COVID-19. <https://www.hhs.gov/about/news/2020/11/10/hhs-allocates-lilly-therapeutic-treat-patients-mild-moderate-covid-19.html>
- 662)** 2020-11-11 Anwar MM, Badawi AM, Eltablawy NA: Can the coronavirus infection penetrates the brain resulting in sudden anosmia followed by severe neurological disorders? <https://reader.elsevier.com/reader/sd/pii/S2405650220300691?token=2704FCAE9A6F6D340EB856A4E818BA899B840BC12513B2D39B8685B9A829472E4EB406237115DC34E3E457E8AA668EBF&originRegion=us-east-1&originCreation=20220321010145>  
[https://ars.els-cdn.com/content/image/1-s2.0-S2405650220300691-gr1\\_lrg.jpg](https://ars.els-cdn.com/content/image/1-s2.0-S2405650220300691-gr1_lrg.jpg)
- 663)** 2020-11-11 Sidarta-Oliveira D, Jara CP, Ferruzzi AJ, Skaf MS, Velandar WH, Araujo EP, Velloso: SARS-CoV-2 receptor is co-expressed with elements of the kinin-kallikrein, renin-angiotensin and coagulation systems in alveolar cells. *Nature Scientific Reports* 11 November 2020; 10, article number 19522 (2020)b <https://www.nature.com/articles/s41598-020-76488-2>

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- 664) 2020-11-12 Farr C: Bioethicists worry the rich and powerful will get special access to experimental Covid treatments. [www.cnbc.com  
https://www.cnbc.com/2020/11/12/coronavirus-bioethicists-worry-the-rich-and-powerful-will-get-special-access-to-experimental-treatments-.html](https://www.cnbc.com/2020/11/12/coronavirus-bioethicists-worry-the-rich-and-powerful-will-get-special-access-to-experimental-treatments-.html)
- 665) 2020-11-13 Thomas K, Weiland N: Eli Lilly's antibody treatment gets Emergency F.D.A. Approval. The New York Times. <https://www.nytimes.com/2020/11/10/world/the-fda-grants-emergency-authorization-of-eli-lillys-antibody-treatment.html>
- 666) 2020-11-16 U.S. Food & Drug Administration: Recommendations for Investigational COVID-19 Convalescent Plasma. November 16, 2020. <https://web.archive.org/web/20210114142146/https://www.fda.gov/vaccines-blood-biologics/investigational-new-drug-ind-or-device-exemption-ide-process-cber/recommendations-investigational-covid-19-convalescent-plasma>
- 667) 2020-11-16 U.S. Food & Drug Administration: Investigational COVID-19 Convalescent Plasma – Guidance for Industry. <https://web.archive.org/web/20201117201040/https://www.fda.gov/media/136798/download>
- 668) 2020-11-17 O'Donnell C, Threlfall A: Regeneron says Roche successfully tested manufacture of COVID-19 drug used on Trump. Reuters. <https://www.reuters.com/article/us-health-coronavirus-regeneron/regeneron-says-roche-successfully-tested-manufacture-of-covid-19-drug-used-on-trump-idUSKBN27X2T5>
- 669) 2020-11-18 **Andrus CH**: 1 Dear Mr President PLEASE COVID-19 Convalescent Plasma NOW 11-17-2020. U.S. Copyright Office, 2020-11-18, TXu002232947. [https://web.archive.org/web/20210904021628/https://cocatalog.loc.gov/cgi-bin/Pwebrecon.cgi?v1=3&ti=1%2C3&Search\\_Arg=andrus+charles+h&Search\\_Code=NALL&CNT=25&PID=py6zcgaddPxEbahiUXXmsV0vRNwjXMy&SEQ=20210512081735&SID=2](https://web.archive.org/web/20210904021628/https://cocatalog.loc.gov/cgi-bin/Pwebrecon.cgi?v1=3&ti=1%2C3&Search_Arg=andrus+charles+h&Search_Code=NALL&CNT=25&PID=py6zcgaddPxEbahiUXXmsV0vRNwjXMy&SEQ=20210512081735&SID=2)
- 670) 2020-11-20 CNBC Squawk Box: Former FDA chief Gottlieb says remdesivir still provides treatment benefit for hospitalized Covid-19 patients. <https://www.cnbc.com/video/2020/11/20/former-fda-chief-gottlieb-says-remdesivir-still-provides-treatment-benefit-for-hospitalized-covid-19-patients.html>
- 671) 2020-11-21 Langreth R, LaVito A: Regeneron gets emergency U.S. clearance for Covid-19 therapy. Bloomberg. <https://www.bloomberg.com/news/articles/2020-11-22/regeneron-gets-emergency-u-s-clearance-for-covid-19-therapy>
- 672) 2020-11-21 Hinton DM: U.S. Food & Drug Administration Letter to Regeneron Emergency Use Authorization (EUA) regarding casirivirumab and imdevimab cocktail. November 21, 2021. <https://www.fda.gov/media/143891/download>

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- 673) 2020-11-21 Food and Drug Administration: Coronavirus (COVID-19) update: FDA authorizes monoclonal antibody for treatment of COVID-19. FDA news release, November 21, 2020. <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-monoclonal-antibodies-treatment-covid-19>
- 674) 2020-11-22 Fauci A: Transcript: Anthony Fauci on “Face the Nation,” November 22, 2020. <https://www.cbsnews.com/news/transcript-anthony-fauci-on-face-the-nation-november-22-2020/>
- 675) 2020-11-22 U.S. Food & Drug Administration: Fact sheet for health care providers emergency use authorization (EUA) of Casirivimab and Imdevimab. <http://web.archive.org/web/20201122011932/https://www.fda.gov/media/143892/download>  
*Please note that this fact sheet regarding Regeneron’s monoclonal antibody cocktail exists to this day. The criteria for administration of casirivimab and imdevimab in the Black Box is stated for only in patients who have mild to moderate symptoms outside of hospital “...at high risk for progressing to severe COVID-19 and/or hospitalization...” This is arbitrarily based on a physician’s ability to predict the future outcome of the individual patient regarding administration to or withholding from early in the disease process of the individual patient and has led to withholding of casirivimab and imdevimab and thus de facto rationing of a safe treatment that should be available to all people who become COVID-19 positive within 72 hours of positivity.*
- 676) 2020-11-21 Regeneron: Regeneron’s casirivimab and imdevimab antibody cocktail for COVID-19 is first combination therapy to receive FDA Emergency Use Authorization. <https://investor.regeneron.com/news-releases/news-release-details/regenerons-regen-cov2-first-antibody-cocktail-covid-19-receive>
- 677) 2020-11-23 Higgins-Dunn N: Regeneron will provide 300,000 doses of Covid treatment for U.S. by early January, CEO Schleifer says. CNBC Health and Science, published Mon, Nov 23, 2020, 10:20 AM EST, updated Mon, Nov 23, 2020, 11:14 AM EST. <https://www.cnbc.com/2020/11/23/regeneron-will-provide-300000-doses-of-covid-treatment-for-us-by-early-january-ceo-schleifer-says.html#:~:text=Squawk%20Box-.Regeneron%20will%20provide%20the%20U.S.%20with%20300%2C000%20doses%20of%20its,treatment%2C%20called%20REGN%2DCOV2.>

[Regeneron](#) will provide the U.S. with 300,000 doses of its newly authorized [Covid-19](#) antibody treatment by early January, the company’s CEO, Dr. Leonard Schleifer, said Monday.

The Food and Drug Administration on Saturday [granted an emergency use](#) authorization for the company’s antibody treatment, called REGN-COV2. The experimental therapy was given to President [Donald Trump](#) when he contracted the coronavirus in October.

In July, the federal government, as part of the Trump administration's Operation Warp Speed, [gave Regeneron \\$450 million](#) in funding to support manufacturing of the drug.

Schleifer told CNBC's "[Squawk Box](#)" on Monday that the company has 80,000 doses of its antibody treatment immediately ready for distribution. The federal government will be responsible for allocating the doses to the states "proportion to the need and amount of Covid," he said.

After January, Regeneron will have the ability to supply 100,000 doses every month, Schleifer said. The company is also conducting experiments to determine whether the dosage can be cut in half, which would eventually double the amount of available doses to 200,000 every month if proven effective, he said.

- 678)** 2020-11-23 Samad N, Sodunke TE, Banna HA, Sapkota A, Fatema AN, Iskandar K, Jahan D, Hardcastle TC, Nusrat T, Chowdhury TS, Haque M: Convalescent plasma therapy for management of COVID-19: Perspectives and deployment in the current global pandemic. Dovepress. <https://www.dovepress.com/convalescent-plasma-therapy-for-management-of-covid-19-perspectives-an-peer-reviewed-fulltext-article-RMHP>

Extensive review of the world literature outlining both the pros, cons, and mixed outcomes in the utilization of Convalescent Plasma.

- 679)** 2020-11-24 Simonovich VA, Burgos Pratz LD, Scibona P, Beruto MV, Vallone MG, Vazquez C, Savoy N, Giunta, Perez LG, Sanchez M.L., Gamarnik AV, Ojeda DS, Santoro DM, Camino PJ, Antelo S, Raineo K, Vidiella GO, Miyazaki EA, Cornistein W, Trabadelo OA, Spotti M, Funtowicz G, Scordo WE, Losso MH, Ferniot I, Pardo PE, Rodriguez E, Rucci P, Pasquali J, Fuentes NA, Esperatti M, Speroni GA, Nannini EC, Matteaccio A, Michelangelo HG, Follmann D, Lane HC, Belloso W, for the PlasmAr Study Group\*: A randomized trial of convalescent plasma in Covid-19 Severe Pneumonia, PlasmAR ClinicalTrials.gov number, NCT04383535. New Engl J Med, NEJM.org, DOI: 10.1056/NEJMoa2031304, November 24, 2020, 1-11. Republished by N Engl J Med, February 18, 2021; 384 (7): 619 – 629. <https://www.nejm.org/doi/pdf/10.1056/NEJMoa2031304?articleTools=true>

- 680)** 2020-11-25 Majra D, Benson J, Pitts J, Stebbing J: Review: SARS-CoV-2 (COVID-19) superspreader events. Journal of Infection 2021; 82: 36-40. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7685932/pdf/main.pdf>

- 681)** 2020-11-25: van Beusekom: M: Studies find no COVID benefit for preventive hydroxychloroquine or for convalescent plasma. CIDRAP, Center for Infectious Disease Research and Policy, University of Minnesota. <https://www.cidrap.umn.edu/news-perspective/2020/11/studies-find-no-covid-benefit-preventive-hydroxychloroquine-or-convalescent>

#### **No differences in clinical status, outcomes**

In the second [study](#), a double-blind, randomized trial, a research team led by scientists with Hospital Italiano de Buenos Aires in Argentina compared the outcomes of 228 hospitalized

COVID-19 patients with severe pneumonia and low oxygen levels at 12 sites who received 500 milliliters of convalescent plasma with those of 105 patients who received a placebo.

- 682) 2020-11-26 U.S. Food & Drug Administration: Recommendations for Investigational COVID-19 Convalescent Plasma. November 16, 2020.  
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- 683) 2020-11-30 Russell MW, Moldoveanu Z, Ogra PL, Mestcecky J: Mucosal Immunity in COVID-19: A neglected but critical aspect of SARS-CoV-2 infection.  
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7733922/pdf/fimmu-11-611337.pdf>
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<https://web.archive.org/web/20210106221857/https://www.fda.gov/media/141477/download>
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<https://www.nejm.org/doi/pdf/10.1056/NEJMra2026131?articleTools=true>
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- 687) 2020-12-07 McGrail S: US Govt purchases additional 650,000 doses of COVID-19 antibody. PHARMANEWS INTELLIGENCE xtelligent HEALTHCARE MEDIA.  
<https://pharmanewsintel.com/news/us-govt-purchases-additional-650000-doses-of-covid-19-antibody>
- 688) 2020-12-08 Schoenfeld-Walker A, Conlen M: Tracking coronavirus infections in The White House and Trump’s Inner Circle. The New York Times, original 11/11/2020 and updated 12/8/2020. <https://www.nytimes.com/interactive/2020/11/11/us/politics/white-house-covid-outbreak.html>
- 689) 2020-12-09 Stolberg SG: Trump and friends got coronavirus care many others couldn’t. Rudolph W. Giuliani became the latest in President Trump’s inner circle to boast about the treatment he received for Covid-19, as hospitals across the country ration care. The New York Times.  
<https://web.archive.org/web/20201210042553/https://www.nytimes.com/2020/12/09/us/politics/trump-coronavirus-treatments.html>



WASHINGTON — Ben Carson, Chris Christie and Donald J. Trump are not the sturdiest candidates to conquer the coronavirus: older, in some cases overweight, male and not particularly fit. Yet all seem to have gotten through Covid-19, and all have gotten an [antibody treatment](#) in such short supply that some hospitals and states are doling it out by lottery.

Now Rudolph W. Giuliani, the latest member of President Trump's inner circle to contract [Covid-19](#), has acknowledged that he received at least two of the same drugs the president received. He even conceded that his "celebrity" status had given him access to care that others did not have.

"If it wasn't me, I wouldn't have been put in a hospital frankly," Mr. Giuliani, the president's personal lawyer, told WABC radio in New York. "Sometimes when you're a celebrity, they're worried if something happens to you they're going to examine it more carefully, and do everything right."

Mr. Giuliani's candid admission once again exposes that Covid-19 has become a disease of the haves and the have-nots. The treatment given to Mr. Trump's allies is raising alarms among medical ethicists as state officials and health system administrators grapple with gut-wrenching decisions about which patients get antibodies in a system that can only be described as rationing.

"We should not have Chris Christie and Ben Carson — and in the case of Carson with intervention by the president — get access," said Arthur Caplan, a medical ethicist who works with drug companies on how to ration scarce medicines, referring to the secretary of housing and urban development's admission that the president "cleared" him for the therapy. "That is not the way to secure public support for difficult rationing systems."

The treatments — a monoclonal antibody developed by Eli Lilly and a cocktail of two monoclonal antibodies developed by Regeneron — [won emergency use authorization](#), or an E.U.A., from the Food and Drug Administration last month for outpatients with "mild to moderate" disease who are at high risk for progressing to severe disease or for being hospitalized.

With cases soaring, the pool of potential patients is vast.

"One of the challenges is the E.U.A. criteria really are so broad, it could be half of the people with Covid could qualify, but there is clearly not enough," said Erin Fox, the senior pharmacy director for University of Utah Health, who has helped her state draft criteria to determine who is eligible for the drugs. "Unfortunately, that leaves each hospital or each state to develop their own rationing criteria."

Even some top officials at the F.D.A. — both career employees and political appointees — have privately expressed concern in recent months that people with connections to the White House appeared to be getting access to the antibody treatments, according to three senior administration officials.

Mr. Giuliani, 76, appeared unaware of the scarcity issues, telling interviewers that politicians have taken masks and business closures too far now that Covid-19 is "a treatable disease."

In fact, the antibody treatments are so scarce that officials in Utah have developed a ranking system to determine who is most likely to benefit from the drugs, while Colorado is using a lottery system. Dr. Matthew Wynia, director of the Center of Bioethics and Humanities at the University of Colorado, said that giving the powerful access was patently unfair.

“That’s one of the reasons why we decided that we would allocate this only through the state and only through this random allocation process,” he said, “so that no one could get a leg up by virtue of their special connections.”

And there are other complicating factors keeping many people from getting the therapies as well. The infusions must be administered in outpatient settings, but infusion centers, which also care for immune-suppressed cancer patients, are loath to treat people who have an infectious disease. And many emergency rooms are so overrun that they do not have the space.

In Utah, Dr. Fox said her hospital had shipped much of the supply of antibodies to rural hospitals, which had more room. Both she and Dr. Wynia in Colorado expressed concern that the therapies might not be distributed equitably across racial and ethnic lines, with hard-hit minority communities not getting their fair share.

The scarcity is such a problem that the National Academies of Sciences, Engineering and Medicine is holding a session next week to help medical professionals sort their way through rationing questions.

“We’ve been trying to get the word out so that as patients might get a positive test they could get information that they might qualify for treatment, but that only works for people with a lot of resources,” Dr. Fox said.

Politicians are not the only ones with resources getting access.

In an interview on Wednesday, one prominent businessman, who spoke on condition of anonymity to avoid harming his reputation, described his aggressive efforts to track down the Regeneron treatment — including calling friends who were hospital executives and hospital donors — after he tested positive last week.

Eventually he was directed to an emergency room in his city, which was expecting him. He was given an infusion of the drug on Monday. He is feeling much better, he said.

Both Mr. Trump and Mr. Christie, a longtime friend of his and former New Jersey governor, got the antibodies before they were approved by the F.D.A. Dr. Caplan, the medical ethicist, said he had no problem with Mr. Trump, 74, getting the therapy — he is, after all, the president, “a special person unto him- or herself.”

But Mr. Christie’s access appeared to be extraordinary. Mr. Christie, 58, was offered participation in a Regeneron clinical trial but turned it down, a person familiar with his treatment said, fearing he might receive a placebo. Instead, he received the Eli Lilly treatment. He is overweight and has asthma, and thus may have been a good candidate,

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Dr. Caplan said, though he wondered if similarly situated patients would have gotten the drug.

Dr. Carson, 69, got the Regeneron cocktail after it was approved, then [took to Facebook](#) last month to say he was “desperately ill” with the coronavirus until the president intervened.

“President Trump was following my condition and cleared me for the monoclonal antibody therapy that he had previously received, which I am convinced saved my life,” he wrote, adding that “we must prioritize getting comparable treatments and care to everyone as soon as possible.”

Mr. Giuliani’s treatment is less clear. Calling into [ABC Radio](#) from his hospital bed on Tuesday, he said specifically that he had received two drugs — remdesivir, which has F.D.A. approval for treatment of Covid-19, and dexamethasone, a steroid.

But he also said he had received the same treatment “cocktail” as the president: “Exactly the same, his doctor sent me here; he talked me into it,” Mr. Giuliani said of Mr. Trump’s physician, adding, “The minute I took the cocktail yesterday, I felt 100 percent better. It works very quickly, wow.”

The therapies are being allocated by the Department of Health and Human Services to states and jurisdictions based, [the department’s website says](#), on a “percentage of the country’s total number of confirmed Covid-19 patients and the total number of confirmed hospitalized patients during a seven-day reporting period.”

California, for example, has been allocated 17,760 doses of [the Eli Lilly therapy](#) and 5,728 doses of the [Regeneron cocktail](#) (the Eli Lilly drug is in greater supply). Maine, with many fewer people and Covid-19 cases, has been allocated 330 and 98 doses of those therapies.

Health Secretary Alex M. Azar II told reporters on Wednesday that so far, 278,000 doses of the two therapies have been allocated. There were almost that many coronavirus cases ([220,225](#)) diagnosed in the United States on Tuesday alone.

Once state and local health agencies determine which hospitals or medical facilities should get the drugs, they are shipped out by a third-party distributor. Then it is up to health care providers to figure out what to do with them. Dr. Peter L. Slavin, the president of Massachusetts General Hospital, said in an interview Tuesday that access there would be by lottery.

“The notion that we are going to be able to treat a significant percentage of the people who qualify for the drug with the drug — it’s not going to happen,” he said.

Noah Weiland and Katie Thomas contributed reporting.

**690)** 2020-12-10 Goldberg M: Covid meds are scarce but not for Trump cronies – Rudy Giuliani got monoclonal antibodies. You probably can’t. The New York Times.  
<https://web.archive.org/web/20201211074255/https://www.nytimes.com/2020/12/10/opinion/coronavirus-giuliani-regeneron.html>

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- 691) 2020-12-13 **Andrus CH**: Letter to the Editor of the New England Journal of Medicine regarding treatment with and synergy of *Passive Immunization* regarding the SARS-CoV-2 virus infection. \*\*\*The editors of NEJM ignored the letter but on January 6, 2021 published the landmark article (appropriately age stratified and COVID-19 Convalescent Plasma given within 72 hours of diagnosis): Libster, et. al.: Early high-titer plasma therapy to prevent severe Covid-19 in older adults, ClinicalTrials.gov, NCT04479163. New Engl J Med, NEJM.org, DOI: 10.1056/NEJMoa2033700, January 6, 2021, 1-9.  
<https://www.nejm.org/doi/pdf/10.1056/NEJMoa2033700?listPDF=true>
- 692) 2020-12-14 Dixit S: Who is Jeffrey Rosen's wife Kathleen Rosen? A look at acting AG's 37-year marriage, children and love for travel. <https://meaww.com/jeffrey-rosen-wife-doctor-kathleen-married-37-years-children-travel>
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<https://www.uptodate.com/contents/overview-of-therapeutic-monoclonal-antibodies/print>
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<https://www.msn.com/en-us/money/markets/antibody-drugs-used-to-treat-trump-others-could-cut-covid-19-hospitalizations-by-half-but-they-re-not-being-used-by-the-general-public/ar-BB1bZaPX?li=BBnba9O>
- 695) 2020-12-16 Hinton DM: BinaxNOW COVID-19 Ag Card. Abbott Diagnostics Scaborough, Inc. <https://www.fda.gov/media/141567/download> and with regards to sensitivity and specificity: Pollreis RE, et al: Evaluation of the Abbott BinaxNOW COVID-19 Test Ag Card for rapid detection of SARS-CoV-2 infection by a local public health district with a rural population. PLOS ONE. 2021-12-02.  
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8638850/pdf/pone.0260862.pdf>
- 696) 2020-12-17 Weinreich DM, Sivapalasingam S, Norton T, Ali S, Gao H, Bhore R, Musser BJ, Soo Y, Rofail D, Im J, Perry C, Pan C, Hosain R, Mahmood A, Davis JD, Turner KC, Hooper AT, Hamilton JD, Baum A, Kyratsous CA, Kim Y, Cook A, Kampman W, Kohli A, Sachdeva Y, Graber X, Kowal B, DiCioccio T, Stahl N, Lipsich L, Braunstein N, Herman G, Yancopoulos GD, for the Trial Investigators. REGN-COV2, a neutralizing antibody cocktail, in outpatients with Covid-19. December 17, 2021 NEJM.org, N Engl J Med 2021; 384:238-251. <https://www.nejm.org/doi/pdf/10.1056/NEJMe2034495?articleTools=true>
- 697) 2020-12-20 **Andrus CH**: E-mail submitted to Dr. Richard Stone, M.D., Chief Medical Executive (acting Under Secretary of the Veterans Health Administration), regarding the WRONG INCLUSION CRITERIA which contradicted the FDA directive of early administration in the course of COVID-19 disease (<72 hours from diagnosis) going forward from August 28, 2020 to the present, regarding Remdesivir (an FDA -approved licensed

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drug: NDA# 214787). This ERRONEOUS DIRECTIVE was still published on the Internet as of October 3, 2021—not having been retracted by the Veterans Health Administration (VHA)—SHAME ON THE VHA! The URL is no longer available.  
[https://vanf.app/CFU\\_PDF/Remdesivir\\_VEKLURY\\_November2020.pdf](https://vanf.app/CFU_PDF/Remdesivir_VEKLURY_November2020.pdf) What use to be at this U.S. Department of Veterans Affairs website is the following page that directed the administration of Remdesivir at the wrong time.

Remdesivir (VEKLURY) CFU

Remdesivir (VEKLURY) CFU

Remdesivir (VEKLURY)	
Criteria for Use	
November 2020	
VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives	
<i>The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&amp;T COMMITTEE AND PHARMACY SERVICES.</i>	
The Product Information should be consulted for detailed prescribing information.	
See the VA National PBM-MAP-VPE Monograph on this drug at <a href="http://www.pbm.va.gov">www.pbm.va.gov</a> or <a href="http://vawww.pbm.va.gov">http://vawww.pbm.va.gov</a> for further information.	
<b>Exclusion Criteria</b>	
If the answer to ANY item below is met, then the patient should NOT receive remdesivir	
<input type="checkbox"/> Treated for COVID-19 as an outpatient	
<input type="checkbox"/> AST or ALT > 5 times the upper limit of normal	
<input type="checkbox"/> Hospitalized patients but NOT requiring supplemental oxygen*	
<input type="checkbox"/> Concomitant use of hydroxychloroquine or chloroquine	
<input type="checkbox"/> Current eGFR < 30 mL/min**	
<b>Inclusion Criteria</b>	
The following must be fulfilled in order to meet criteria for remdesivir	
<input type="checkbox"/> Hospitalized with SEVERE COVID-19 (room air oxygen saturation < 94%, requiring supplemental oxygen or increase from baseline if on chronic oxygen therapy or is requiring invasive or non-invasive ventilation or ECMO)***	
<b>Supplemental Information</b>	
Recommended initial duration of therapy is 5 days, with the potential to extend to 10 days in patients who are not improving or who remain critically ill. Therapy can be discontinued when the patient is appropriate for discharge, even if the full duration of therapy has not been given	
*Use in hospitalized patients with mild to moderate COVID-19 at high risk for progression to severe disease may be appropriate and should be adjudicated on a case by case basis	
**Patients with eGFR < 30 mL/min (or CrCl < 30-50 mL/min depending on the trial) were excluded from clinical trials and routine use is not recommended by the manufacturer. Use may be considered and adjudicated on a case by case basis if the benefit is felt to outweigh the risks, especially when renal function is likely to improve rapidly (e.g. dehydration). The mechanism of calculating renal function can be based on local guidance.	
***Remdesivir alone is not recommended alone for patients on mechanical ventilation or ECMO but may be considered in conjunction with corticosteroids in patients who have recently been intubated, according to the NIH Treatment Guidelines for COVID-19	
Prepared: November 2020. Contact: Kelly Echevarria, PharmD, BCPS, AQ-ID, BCIDP, National Clinical Pharmacy Program Manager, VA Pharmacy Benefits Management Services 10P4P	
Updated version may be found at <a href="#">PBM INTERNET</a> or <a href="#">PBM INTRANET</a>	

1

698) 2020-12-22 Pollard AJ, Bijker EM: A guide to vaccinology: from basic principles to new developments. Nature reviews immunology 2021; 21: 83-100.  
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<https://web.archive.org/web/20201223152514/https://www.nytimes.com/2020/12/23/health/covid-antibody-treatment.html>
- 700) 2020-12-24 Andrus CH: E-mail directed to the New England Journal of Medicine, the Veterans Health Administration, etc. It was ignored!
- 701) 2020-12-24 Goodman KE, Harris AD, Hoffmann DE: Legal challenges to allocating new COVID-19 antibody therapies to those who need them most. Health Affairs Blog.  
<https://www.healthaffairs.org/doi/10.1377/hblog20201222.609517/full/>
- 702) 2020-12-28 Sandborg CI, Hartman GE, Su F, Williams G, Teufe, Wixson N, Larson DB, Donnelly: Optimizing professional practice evaluation to enable a nonpunitive learning health system approach to peer review.  
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7781295/pdf/pqs-6-e375.pdf>
- 703) 2020-12-29 Nickitas P: It shouldn't be this hard to serve your country by David Shulkin. Jewish War Veterans of the United States of America 2020; 74 (4). <https://www.jwv.org/it-shouldnt-be-this-hard-to-serve-your-country-by-david-shulkin/>

# IT SHOULDN'T BE THIS HARD TO SERVE YOUR COUNTRY BY DAVID SHULKIN

By Peter Nickitas, JWV National Judge Advocate

"It Shouldn't Be This Hard to Serve Your Country" describes the public service of the first Jewish-American Secretary of Veterans Affairs, Dr. David Shulkin. Shulkin served as Undersecretary of the VA from 2015 to 2017 and Secretary from 2017 to 2018. Shulkin served as the first chief medical officer of the University of Pennsylvania Health System and CEO of New York's Beth Israel Medical Center before entering public service.

This book makes outstanding reading, as Secretary Shulkin describes his encounters with entrenched officials of the Department of Veterans Affairs (VA) in his work to bring more accountability, veteran-focused care, accessible service, and timely appointments. His accomplishments included updating electronic health records (EHR) systems and expanding Agent Orange treatment to Blue Water Navy veterans who served on ships off the

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shore of Vietnam and suffered diseases induced by the Agent Orange clouds that blew offshore. In his words, he found himself with the choice between continued neglect of veterans based on dwindling scientific evidence as veterans died, or the moral choice, and treat Blue Water Navy veterans. He took the moral choice.

He spent a great deal of energy bringing the 2014 Veteran Access, Choice, and Accountability Act up to date in 2017 and 2018, culminating in the Mission Act. At all times, he fought to ensure quality and coordinate the delegation of some care to private providers without eviscerating the core Veterans Affairs budget for VA medical center care. During his time at Secretary, he even saw patients himself at surprise appointments at VA Medical Centers.

Shulkin says his vision for the future of the VA is “a new model of governance, complete with its own board composed of health care experts, veterans, and business leaders. It should remain a government entity but with a structure that allows it to develop strategies free of political influence.... This new governance structure would mean the end of political appointees. People who serve our veterans should be chosen not on the basis of political ideology or their commitment to a particular elected individual but rather because of relevant experience, competence, and commitment to the mission.”

“It Shouldn’t Be This Hard to Serve Your Country” provides an example of a Jewish-American who as the founders of JWV would say, “redeems the good name of the Jew.” Shulkin took the opportunity for service and made the most of it, to show that we Jewish-Americans are capable of fulfilling acts of Torah-Mitzvot and our civic obligations to our nation, our neighbors, and our fellow veterans and servicemembers, with equal fervor and merit.

*Volume 74. Number 4. 2020*  
DECEMBER 29, 2020

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<https://www.britannica.com/topic/seven-deadly-sins>

**705)** 2020-12-31 McGinley L: Only one covid-19 treatment is designed to keep people out of the hospital. Many overburdened hospitals are not offering it. Because of logistical challenges, only 20 percent of monoclonal antibodies distributed by the government have

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<https://www.nejm.org/doi/pdf/10.1056/NEJMoa2033700?listPDF=true> Republished N Engl J Med, February 18, 2021; 384(7): 610 – 618.

- 707)** 2021-01-07 Wray : FBI MOST WANTED – U.S. Capitol Violence.

<https://www.fbi.gov/wanted/capitol-violence>

## Director Wray's Statement on Violent Activity at the U.S. Capitol Building

January 7, 2021

The violence and destruction of property at the U.S. Capitol building yesterday showed a blatant and appalling disregard for our institutions of government and the orderly administration of the democratic process. As we've said consistently, we do not tolerate violent agitators and extremists who use the guise of First Amendment-protected activity to incite violence and wreak havoc. Such behavior betrays the values of our democracy. Make no mistake: With our partners, we will hold accountable those who participated in yesterday's siege of the Capitol.

Let me assure the American people the FBI has deployed our full investigative resources and is working closely with our federal, state, and local partners to aggressively pursue those involved in criminal activity during the events of January 6. Our agents and analysts have been hard at work through the night gathering evidence, sharing intelligence, and working with federal prosecutors to bring charges. Members of the public can help by providing tips, information, and videos of illegal activity at [fbi.gov/USCapitol](https://www.fbi.gov/USCapitol). We are determined to find those responsible and ensure justice is served.

- 708)** 2021-01-08 BBC News-Science: What is blood plasma and how does it treat Covid-19?

<https://www.bbc.com/news/av/science-environment-54665716>

- 709)** 2021-01-08 Eli Lilly and Company: 2020 Updates: Lilly's global COVID-19 response.

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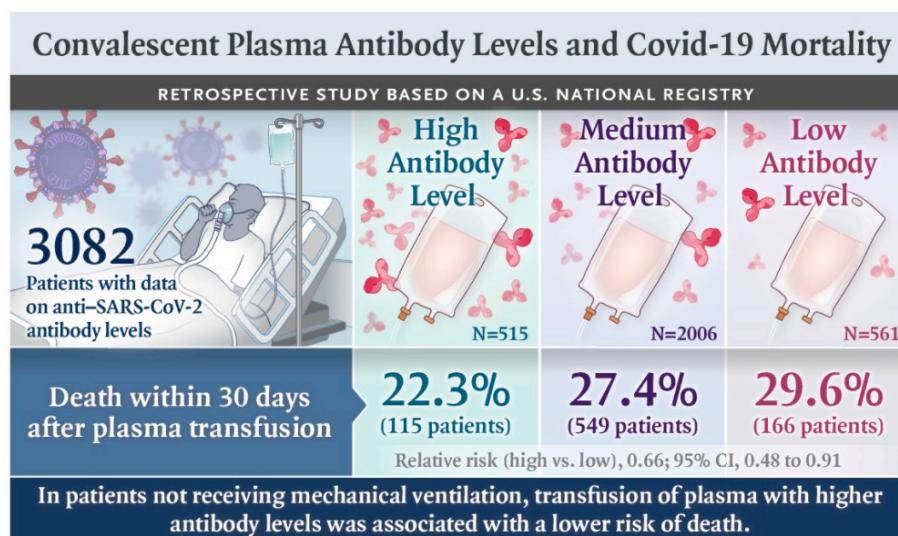
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- 711)** 2021-01-12 Regeneron: Regeneron announces U.S. Government agreement to purchase additional COVID-19 antibody cocktail doses. <https://investor.regeneron.com/index.php/news-releases/news-release-details/regeneron-announces-us-government-agreement-purchase-additional>
- 712)** 2021-01-12 Kokic G, Hillen HS, Tegunov D, Dienemann C, Seitz F, Schmitzova J, Farnung L, Siewert A, Hobartner C, Cramer P: Mechanism of SARS-CoV-2 polymerase stalling by remdesivir. *Nature Communications* (2021)12:279 <https://doi.org/10.1038/s41467-020-20542-0>. <https://www.nature.com/articles/s41467-020-20542-0.pdf>
- 713)** 2021-01-13 Joyner MJ, Carter RE, Senefeld JW, Klassen SA, Mills JR, Johnson PW, Theel ES, Wiggins CC, Bruno KA, Klompas AM, Lesser ER, Kunze KL, Sexton MA, Diaz Soto JC, Baker SE, Shepherd JRA, van Helmond N, Verdun NC, Marks P, van Buskirk CM, Winters JL, Stubbs JR, Rea FR, Hodge DO, Herasevich V, Whelan ER, Clayburn AJ, Larson KF, Ripoll JG, Andersen KJ, Buras MR, Vogt MNP, Dennis JJ, Regimbal RJ, Bauer PR, Blair JE, Paneth NS, Fairweather D, Wright RS, Casadevall A, *et. al.*: Convalescent plasma antibody levels and the risk of death from Covid-19. *N Engl J Med*, January 13, 2021, at NEJM.org; then republished *N Engl J Med* 2021; 384:1015-1027. <https://www.nejm.org/doi/full/10.1056/NEJMoa2031893>

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M.J. Joyner et al. 10.1056/NEJMoa2031893

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## Conclusions

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Among patients hospitalized with Covid-19 who were not receiving mechanical ventilation, transfusion of plasma with higher anti-SARS-CoV-2 IgG antibody levels was associated with a lower risk of death than transfusion of plasma with lower antibody levels. (Funded by the department of Health and Human Services and others; ClinicalTrials.gov number, NCT04338360.

- 714) 2021-01-13 McCarthy CG, Wilczynski S, Wenceslau CF, Webb RC: A new storm on the horizon in COVID-19: Bradykinin-induced vascular complications.  
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7834250/pdf/main.pdf>
- 715) 2021-01-14 Rodriguez A: US officials urge Americans to ask their doctors about monoclonal antibodies for COVID. But is it too little, to late? USA TODAY  
<https://www.usatoday.com/story/news/health/2021/01/14/monoclonal-antibodies-covid-full-supply-but-lack-demand-hhs/4159950001/>
- 716) 2021-01-15. U.S. Department of Health and Human Services: Monoclonal antibodies for high-risk covid positive patients combat. COVID.hhs.gov (First documented posting by on the Internet Archive (Wayback Machine) on January 15, 2021 which was the week of the delayed posting by the U.S. Copyright Office of Andrus CH: *I Dear Mr President PLEASE COVID-19 Convalescent Plasma NOW 11-17-2020*. Registration Number / Date TX002232947 / 2020-11-18.) <https://combatcovid.hhs.gov/i-have-covid-19-now/monoclonal-antibodies-high-risk-covid-19-positive-patients>
- 717) While this URL was the posting throughout from January 15, 2021 to the present (May18, 2021) the website has changed in information. The “combatCOVID.hhs.gov” website on January 15, 2021 can be found using the Wayback Machine of the Internet Archive: <http://web.archive.org/web/20210115154152/https://combatcovid.hhs.gov/i-have-covid-19-now/monoclonal-antibodies-high-risk-covid-19-positive-patients> . This website is explicit DHHS qualitative rationing without justification and also implicit rationing as few Americans know to access this site:

If you have COVID-19, you may be at high-risk of your symptoms getting worse. Based on your age, the length of your symptoms, and some medical conditions, you may be eligible for certain treatment or qualify for clinical studies.

#### WHAT IS A MONOCLONAL ANTIBODY?

Our bodies naturally make antibodies to fight infection. Monoclonal antibodies are made in a laboratory and are given to patients directly through an infusion. These treatments may help patients who are at high risk for severe illness avoid hospitalization and/or disease progression.

COVID-19 monoclonal antibody treatments are different from COVID-19 vaccines. Vaccines provide active immunity by triggering the body’s natural immune response. Vaccines often require two shots and time for the body to be able to develop this immune response. When you have the virus, monoclonal antibody treatments give the antibodies that the body needs to protect itself.



## AM I A CANDIDATE FOR TREATMENT?

The FDA has authorized two monoclonal antibody treatments for emergency use [bamlanivimab](#), [casirivimab and imdevimab](#). These treatments could help the immune system respond more effectively to the virus. Your healthcare provider can help you determine if you're a candidate for treatment.

Monoclonal antibody treatments have been authorized by the FDA for patients who have tested positive for COVID-19 in the last ten days, who are 12 years of age and older, and who are at high risk for progressing to severe COVID-19 and/or hospitalization.

This also includes people who are 65 years of age or older or who have certain chronic medical conditions.

## MILESTONE

Over 600,000 monoclonal antibodies have been distributed to healthcare facilities, nationwide.

### DID YOU KNOW...

**You're eligible to be treated with the monoclonal antibody if you are:**

- 65 years of age or older
- 55 years or older with:
  - Heart disease
  - OR high blood pressure
  - OR COPD/chronic respiratory disease, including asthma.
- Any age with:
  - Obesity (a body mass index [BMI] of 35 or higher)
  - OR diabetes (Type 1 or Type 2)
  - OR chronic kidney disease
  - OR a weakened immune system
  - OR you're taking medicine that weakens your immune system.

**Your child is eligible to be treated with the monoclonal antibody if he or she is:**

- 12 to 17 years of age and at least 40 kg (88 pounds) with:
  - Obesity (a BMI greater than or equal to 85 percent of patients of the same age and gender)
  - OR regularly uses medical technology such as a ventilator or feeding tube
  - OR have a developmental condition like cerebral palsy
  - OR sickle cell disease
  - OR congenital or acquired heart disease
  - OR asthma/chronic respiratory problems requiring daily medication for control.

### How Can I Get Monoclonal Antibodies?



**Step 1:** Test positive  
for COVID-19 in  
the last 10 days.



**Step 2:** Receive a  
referral from your  
healthcare provider.

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**Prevention:** *Active Immunization:* Vaccines



### Step 3: Locate an available infusion location.

Patients who have had symptoms for 10 days or less should be referred for treatment by their healthcare providers and directed to available infusion locations.

- 718) 2021-01-15 U.S. Food & Drug Administration: Recommendations for Investigational COVID-19 Convalescent Plasma. January 15, 2021.  
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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*  
**Prevention:** *Active Immunization:* Vaccines

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[https://natap.org/2021/COVID/020321\\_02.htm](https://natap.org/2021/COVID/020321_02.htm)

INDIANAPOLIS, Jan. 21, 2021 /PRNewswire/ -- Bamlanivimab (LY-CoV555) significantly reduced the risk of contracting symptomatic COVID-19 among residents and staff of long-term care facilities, Eli Lilly and Company (NYSE: LLY) announced. The Phase 3 BLAZE-2 COVID-19 prevention trial - conducted in partnership with the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), and the COVID-19 Prevention Network (CoVPN) - enrolled residents and staff at skilled nursing and assisted living facilities, commonly referred to as nursing homes, across the U.S. The 965 participants who tested negative for the SARS-CoV-2 virus at baseline (299 residents and 666 staff) were included in the analysis of primary and key secondary endpoints for assessing prevention, while the 132 participants (41 residents and 91 staff) who tested positive for the virus at baseline were included in exploratory analyses for assessing treatment, adding to the growing body of evidence for treatment with bamlanivimab. All participants were randomized to receive either 4,200 mg of bamlanivimab or placebo.

After all participants reached 8 weeks of follow-up, there was a significantly lower frequency of symptomatic COVID-19 (the primary endpoint) in the bamlanivimab treatment arm versus placebo (odds ratio 0.43, p=0.00021). Results for all key secondary endpoints also reached statistical significance in both the overall and resident populations.

For the pre-specified subgroup of nursing home residents, there was also a significantly lower frequency of symptomatic COVID-19 in those treated with bamlanivimab versus placebo in this important population (odds ratio 0.20; p=0.00026). These results suggest that residents randomized to bamlanivimab have up to an 80 percent lower risk of contracting COVID-19 versus residents in the same facility randomized to placebo. Results from exploratory analyses of viral load in the treatment group were consistent with previously disclosed data from BLAZE-1

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evaluating bamlanivimab as an outpatient treatment for recently diagnosed COVID-19.

Among the 299 residents in the prevention group, there were 4 deaths attributed to COVID-19 at the time of death, and all occurred in the placebo arm. There were no COVID-19 attributed deaths in the bamlanivimab arm. Among the 41 residents in the treatment group, there were 4 deaths, and all occurred in the placebo arm with none in the bamlanivimab arm. Over the entire trial, there were a total of 16 deaths reported, including deaths not related to COVID-19, and all deaths were residents (11 deaths in placebo arm and 5 in bamlanivimab arm).

"We are exceptionally pleased with these positive results, which showed bamlanivimab was able to help prevent COVID-19, substantially reducing symptomatic disease among nursing home residents, some of the most vulnerable members of our society," said Daniel Skovronsky, M.D., Ph.D., Lilly's chief scientific officer and president of Lilly Research Laboratories. "These data provide important additional clinical evidence regarding the use of bamlanivimab to fight COVID-19 and strengthen our conviction that monoclonal antibodies such as bamlanivimab can play a critical role in turning the tide of this pandemic. We're glad bamlanivimab is already available as a treatment for patients at high risk for progressing to severe COVID-19 illness or hospitalization, including those in nursing homes, and look forward to working with regulators to explore expanding the emergency use authorization to prevent the spread of COVID-19 in these facilities."

*Original announcement from Lilly of January 21, 2021:* <https://investor.lilly.com/node/44291/pdf>

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Dear Dr. Birx:

On March 24, 2020, while there was much discussion and debate about COVID-19 convalescent plasma and the possible development of monoclonal antibodies against COVID-19, U.S. Medicine and the Government failed to explain to the American public the differences and individual utilities of *Active Immunization* (vaccines to stimulate patient antibody production) and *Passive Immunization* (provision of convalescent plasmas, convalescence sera, and immunoglobins from other species providing already formed antibodies (IgM, IgG, and IgA) against the virus in COVID-19 immunologically naïve patients immediately within 72 hours of diagnosis (testing positive).

In your interview with Margaret Brennan, you stated the following:

DR. BIRX: Well, what I do know and what was reassuring to me all along is I knew this would be studied. I knew that the emails, the reports that I wrote, the request to expand testing, the **how to improve therapeutics**,

all of that, all of that would eventually come to light. Maybe not in my lifetime.

Last summer you stated that we should collect 500,000 units of convalescent plasma to prepare for the spike in the Fall –well, we as a nation didn’t do that. In fact, as you are a clinical Immunologist, you are very well aware of **Passive Immunization** in the initial early treatment (<72 hours) with the contraction of or exposure to a disease without any true alternate therapy as soon as possible (<72 hours) [e.g.: rabies, hydrops fetalis (Rhogam within 72 hours to an Rh negative mother at delivery of the prior pregnancy, snake bites, etc)]. In fact, to withhold **Passive Immunization** (RhoGAM) from a newly delivered Rh negative mother is considered malpractice. By semantics and legal obfuscation, over the course of the last 10 months, the American public has been led down the rabbit hole by the Medical and Research community, the “Industry”, and the Federal Government by not officially providing any timely-appropriate immunotherapy in the treatment of COVID-19 positivity with **Passive Immunization** until recently:

1. In March 2020, the FDA declared COVID-19 Convalescent Plasma *Investigational* instead of a *Biosimilar* biologic;
2. On March 24, 2020 the FDA outlined **Eligibility Criteria** in the late treatment of severe COVID-19 disease with COVID-19 Convalescent Plasma (at deaths door – when the viremia is not the cause of death but rather the SARS pathophysiology) justifying this choice of late administration as the US did not have enough recovered convalescent patients (>14 days) ;
3. In early April 2020, the Mayo Clinic with the FDA offered COVID-19 Convalescent Plasma in the Expand Access protocol Convalescent Plasma COVID-19 (Coronavirus) Treatment (uscovidplasma.org) using the at-deaths-door **Eligibility Criteria** (“expanded access” is really “compassionate use”—so, therefore, any resultant data cannot officially be used for completion of a Phase I Clinical Trial). Over 94,000 units of COVID-19 plasma were given AT THE THERAPEUTICALLY WRONG TIME only to severely-effected patients with the SARS pneumonitis or MSOF.
4. Throughout the last 11 months, the DHHS through the FDA and NIH has equated Safety Trials (Phase I trials) with Efficacy Trials (Phase II/III) so that there are no “Completed” Phase I (safety) trials with regards to COVID-19 biologics. Who should explain to the American people if the NIH plans on evading *ad infinitum* the “Right to Try” Law PL-115-176? Has not a **bad** precedent been set by not declaring a “completed” Phase I Trial with regards to COVID-19 Convalescent Plasma? Will any NIH protocol or FDA new drug/biologic Phase II/III trial and in any future research **not** be required to abide by the “Right to Try” Law, PL-115-176? In essence, the FDA and NIH are in violation, at least in violation of the intent of federal law PL-115-176 which requires a “Completed” Phase I Trial **only**

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for application of PL-115-176. Forcing patients to participate in Placebo-controlled Phase II/ III Trials is coercion which is prohibited by every IRB in the nation. On August 12, 2020 in the St. Louis Post-Dispatch, the following quote involving one of the FDA-Mayo Clinic's named investigators was documented:

But the program has also had an unintended consequence: Patients aren't signing up for controlled trials, which compare outcomes for patients randomly assigned to receive the treatment with those who receive a placebo.

"If you have a 50% chance of getting either the stuff or nothing, which would you choose?"

[https://www.stltoday.com/lifestyles/health-med-fit/coronavirus/two-washington-u-doctors-lead-national-effort-to-study-new-covid-19-treatment/article\\_ccec0f56-4493-5a26-8601-45e35d364b2d.html](https://www.stltoday.com/lifestyles/health-med-fit/coronavirus/two-washington-u-doctors-lead-national-effort-to-study-new-covid-19-treatment/article_ccec0f56-4493-5a26-8601-45e35d364b2d.html)

No IRB, worth their salt, should ever approve of such a concept of coercion in any Clinical Trial; and the FDA should not only shut down any Clinical Trial with such flagrant coercion but also censure, if not shut down, any IRB that permitted such coercion.

5. All summer, the FDA kept announcing they were close to releasing an EUA regarding COVID-19 Convalescent Plasma. President Trump went to the American Red Cross at the end of July confirming the need in his mind and that of the President's COVID-19 Taskforce for COVID-19 Convalescent Plasma. The announcement of the EUA was delayed until it would be announced on Sunday, August 23, 2020, by President Trump on the eve of the Republican National Convention. The next day, the NIH COVID-19 Guidelines Panel condemned the EUA for lacking scientific rigorous analysis (being based on Expanded Access/*Compassionate Use* protocol data from the FDA/Mayo clinic study). In the most-recent guidelines of the NIH COVID-19 Guideline Panel of January 14, 2021, the NIH COVID-19 Guidelines Panel is now hedging its bets by hiding under "Convalescent Plasma" *Last Update October 9, 2020*:

#### Rationale for Recommendation

Currently, there are insufficient data from well-controlled, adequately powered, randomized clinical trials to evaluate the efficacy and safety of convalescent plasma for the treatment of COVID-19. However, >70,000 patients in the United States have received COVID-19 convalescent plasma through the Mayo Clinic's Expanded Access Program (EAP), which was designed primarily to provide broad access to investigational convalescent plasma and thus did not include an untreated control arm. Both the Food and Drug Administration (FDA) and the Mayo Clinic performed retrospective, indirect evaluations of efficacy by using the Mayo Clinic EAP data, hypothesizing that patients who received plasma units with higher titers of SARS-CoV-2 neutralizing antibodies would have better clinical outcomes than those who received plasma units with lower antibody titers. **The results of their analyses suggest that convalescent plasma with**

**high antibody titers may be more beneficial than low-titer plasma in nonintubated patients, particularly when administered within 72 hours of COVID-19 diagnosis.**

(While the Mayo Clinic's Expanded Access Program (EAP) did not have an official "untreated control arm" since it was *Compassionate Use* only, the Mayo Clinic's EAP Safety Update in June 2020 of 20,000 patients actually included a total of 21,987 infused patients with 1,987 patients not completing the post-infusion 7-day period and 8,130 being untreated. When one back-calculates varying the possible mortality rate in this untreated group, a mortality rate of 8.7% or greater would have been statistically significant with less than a 0.05% confidence level. *But, unfortunately, the Mayo Clinic's Expanded Access Program* did not even qualify as a "Completed Phase I Study" by the "purism" semantics of the NIH. Dr. Birx, the FDA has final statutory say over all new drugs and biologics, **NOT** the NIH.)

6. The Chief Scientist of the FDA, Rear Admiral Hinton, finally removed the severity criteria by removing completely the ***Eligibility Criteria*** regarding Remdesivir on August 28, 2020 (the VA Central Office pharmacy formulary panel was still insisting on the severity ***Eligibility Criteria*** as the only criteria for those eligible for Remdesivir in November 2020--three months after it was rescinded by Rear Admiral Hinton). [Veklury \(remdesivir\) EUA Letter of Approval, reissued 10/22/2020 \(fda.gov\)](#)
7. On September 2, 2020, the FDA removed completely without public awareness the severe disease ***Eligibility Criteria*** for COVID-19 Convalescent Plasma. Many institutions are still applying the severe disease ***Eligibility Criteria*** to this day--thus refusing patients COVID-19 Convalescent Plasma treatment when they first become COVID-19 positive and present to the local ER—including recently a patient with a 104 fever and uncontrollable cough that I personally know. (i.e.: The FDA's complete removal of the ***Eligibility Criteria*** after September 2, 2020 can be demonstrated by viewing an example of the U.S. Food & Drug Administration's website: *Recommendations for Investigational COVID-19 Convalescent Plasma* by comparing the most recent URL: <https://www.fda.gov/vaccines-blood-biologics/investigational-new-drug-ind-or-device-exemption-ide-process-cber/recommendations-investigational-covid-19-convalescent-plasma> by copying and pasting the URL into the Internet Archive (Wayback Machine) and displaying a URL before September 2, 2020 in which the severe disease ***Eligibility Criteria*** was outlined from April 2020 to September 2, 2020: [Recommendations for Investigational COVID-19 Convalescent Plasma | FDA \(archive.org\)](#) :

#### Patient Eligibility

To facilitate requests for eINDs for use of COVID-19 convalescent plasma to treat patients, health care providers seeking an emergency IND may want to consider the eligibility criteria used for the **National Expanded Access Treatment Protocol**[External Link Disclaimer](#). These criteria include:

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- Laboratory confirmed COVID-19
- Severe or immediately life-threatening COVID-19, for example,
  - Severe disease is defined as one or more of the following:
    - shortness of breath (dyspnea),
    - respiratory frequency  $\geq 30/\text{min}$ ,
    - blood oxygen saturation  $\leq 93\%$ ,
    - partial pressure of arterial oxygen to fraction of inspired oxygen ratio  $< 300$ ,
    - lung infiltrates  $> 50\%$  within 24 to 48 hours
  - Life-threatening disease is defined as one or more of the following:
    - respiratory failure,
    - septic shock,
    - multiple organ dysfunction or failure
- Informed consent provided by the patient or healthcare proxy.

8. Before the EUAs were issued by Rear Admiral Hinton regarding the Regeneron monoclonal cocktail (casirivimab and imdevimab) and Eli Lilly monoclonal antibody bamlanivimab, on October 26, 2020 Eli Lilly asked the FDA to exclude the use of their monoclonal antibody in patients with any signs of severity of associated illness parameters such as any new requirement of oxygen supplementation in any non-COPD patient or increase in amount of oxygen supplementation in COPD patients.

9. Rear Admiral Hinton issued EUAs for Eli Lilly's bamlanivimab (<https://www.fda.gov/media/143602/download>) on November 10, 2020 and for Regeneron's casirivimab and imdevimab on November 21, 2020 (<https://www.fda.gov/media/143891/download>). Both EUAs state the following (I will use the Regeneron's monoclonal cocktail as the example as President Trump had received this "experimental" cocktail in early October 2020 prior to the issuing of these EUAs):

## II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited as follows:

- Distribution of the authorized casirivimab and imdevimab will be controlled by the United States (U.S.) Government for use consistent with the terms and conditions of this EUA. Regeneron will supply casirivimab and imdevimab to authorized distributor(s)<sup>4</sup>, who will distribute to healthcare facilities or healthcare providers as directed by the U.S. Government, in collaboration with state and local government authorities, as needed;
- The casirivimab and imdevimab covered by this authorization will be used only by healthcare providers to treat mild to moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progressing to severe COVID-19 and/or hospitalization;
- Casirivimab and imdevimab may only be administered together;
- **Casirivimab and imdevimab is not authorized for use in the following patient populations<sup>5</sup>:**

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- Adults or pediatric patients who are hospitalized due to COVID-19, or
- Adults or pediatric patients who require oxygen therapy due to COVID19, or
- Adults or pediatric patients who require an increase in baseline oxygen flow rate due to COVID-19 in those patients on chronic oxygen therapy due to underlying non-COVID-19-related comorbidity.

• Casirivimab and imdevimab may only be administered in settings in which health care providers have immediate access to medications to treat a severe infusion reaction, such as anaphylaxis, and the ability to activate the emergency medical system (EMS), as necessary.

• The use of casirivimab and imdevimab covered by this authorization must be in accordance with the dosing regimens as detailed in the authorized Fact Sheets.

10. On November 24, 2020, in *NEJM* was published: Simonovich VA, *et al*: [A Randomized Trial of Convalescent Plasma in Covid-19 Severe Pneumonia \(nejm.org\)](#) which is an outstanding, well-thought-out prospective trial using the discontinued/withdrawn severely-ill COVID-19 patient ***Eligibility Criteria*** in which all COVID-19 Convalescent Plasma was given only in patients with severe COVID-19 SARS pneumonitis. Unfortunately, the authors failed to mention in their paper's abstract conclusion that the outcome of the study was based on patients given COVID-19 Convalescent Plasma with only severe SARS pneumonitis—following the previously omitted (September 2, 2020) severe patient ***Eligibility Criteria*** in which ***Passive Immunization*** was administered at the WRONG TIME—that is at deaths-door instead of within 72-hours of COVID-19 positivity!:

#### CONCLUSIONS

No significant differences were observed in clinical status or overall mortality between patients treated with convalescent plasma and those who received placebo. (PlasmAr ClinicalTrials.gov number, [NCT04383535](#). [opens in new tab.](#))

11. I wrote a Letter to the Editors of *The New England Journal of Medicine (NEJM)* regarding Simonovich VA, *et al* and included those I could access with regards to e-mails in the DHHS, the VA, and Saint Louis University SOM as I am a Professor of Surgery and the General Surgery Residency site director at the St. Louis (John Cochran) VAMC. I never got a response back from the *NEJM* but on January 6, 2021, the landmark article by Libster R, *et al*: [Early High-Titer Plasma Therapy to Prevent Severe Covid-19 in Older Adults \(nejm.org\)](#) demonstrated a statistically significant decrease in mortality and severity of illness in a specific age group (the elderly) when COVID-19 Convalescent Plasma was given within 72 hours (**AT THE RIGHT TIME**) of detection of COVID-19 positivity. As is stated in the conclusion of the abstract in this article:

#### CONCLUSIONS

Early administration of high-titer convalescent plasma against SARS-CoV-2 to mildly ill infected older adults reduced the progression of

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Covid-19. (Funded by the Bill and Melinda Gates Foundation and the Fundación INFANT Pandemic Fund; Dirección de Sangre y Medicina Transfusional del Ministerio de Salud number, PAEPCC19, Plataforma de Registro Informatizado de Investigaciones en Salud number, 1421, and ClinicalTrials.gov number, NCT04479163.)

One of my fellow Attending Surgeons at the VA came to my office after my e-mail cover letter to my Letter to the Editors to *NEJM* and stated that I had every right under the first Amendment to communicate whatever I wished but I was just making a fool of myself as there were much smarter people than me involved in setting standards for COVID-19 therapy. The next night, I got a call from an administrator at Saint Louis University SOM (SLUSOM) stating I was only allowed to speak about COVID-19 Convalescent Plasma with other faculty members of SLUSOM and the physicians, nurses, and other healthcare personnel at the local VA--St. Louis (John Cochran) VAMC and to STOP calling Washington DC. He then asked me unknowingly why I had included e-mails to Harvard. I responded that this e-mail was concerned my cover letter regarding my letter to the Editors of *The New England Journal of Medicine*. He responded: Oh—speak only with those in the local VA and Saint Louis University.

[Please note I attached a slide of mortality due to COVID-19 by age range between March and November 2020. First, the mortality percentages by age range had not changed over those 9 months suggesting the USA has not diminished the death rate by any therapy employed so far in any age group over 40 years of age. Second, you will note, the mortality from 40 to 90 years increases by 0.67% per year:  $y = 0.0067x - 0.2647$ ,  $R^2 = 0.9676$ ; and, below age 40, the mortality rate increases only by 0.04% per year to maximally 0.12%/year:  $y = 0.0004x - 0.0023$ ,  $R = 0.7987$ . Once again, as the mortality rates in all range groups over the age of 40 have not changed over the last 10 months, the late administration of **Passive Immunization** to the majority of the hundred thousand patients that received COVID-19 Convalescent Plasma was given at the WRONG TIME using the now rescinded FDA patient **Eligibility Criteria**--such administration at the WRONG TIME did not make a substantial impact. What this also implies is that sending the children and young adults back to in-school-learning will be relatively safe for the children—mortality rate 0.04% increase per year when compared with adults over age 40 years—mortality rate 0.67% per year (which is 16x higher than in children). This presents the possibility to generate a vector repository in our children who could then transmit COVID-19 to their parents, grandparents, and other adults who have a higher risk of severity of disease and death.]

12. The *NEJM* landmark article of January 6, 2021 by Libster R, *et al*: [Early High-Titer Plasma Therapy to Prevent Severe Covid-19 in Older Adults \(nejm.org\)](https://www.nejm.org/doi/full/10.1056/NEJMoa2025384) was overshadowed by the events that occurred later in the day in Washington

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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*  
**Prevention:** *Active Immunization:* Vaccines

D.C. Ironically, on January 14, 2021, *USA Today* ran an article: Rodriguez A: US officials urge Americans to ask their doctors about monoclonal antibodies for COVID. But is it too little, too late? [Monoclonal antibodies for COVID in full supply, but lack demand: HHS \(usatoday.com\)](#) . On January 17, 2021 in *Infection Control Today*, Kavanagh K: [As Vaccine Rollout Stalls, Move Monoclonal Antibodies Into COVID Fight \(infectioncontrolday.com\)](#) using monoclonal antibodies used prophylactically to protect in exposures. **Both** monoclonal antibodies and COVID-19 Convalescent Plasma are **Passive Immunization** therapeutic agents and should therefore be administered at the same appropriate time-- <72 hours from symptomatology or COVID-19 positivity instead of only to patients at deaths-door. Over the last 10 months, the American public has been so misdirected (or lied to) by the ambiguity in the terminology and focus on vaccine production that few realize that **Passive Immunization** includes polyclonal antibodies (COVID-19 Convalescent Plasma) and monoclonal antibodies which should be given to all immediately when they become COVID-19 positive!

13. As is now being reported in the press, mutations of COVID-19 are developing around the World that may make the present vaccines and monoclonal antibodies ineffective.

14. As we go forth, the Standard-of-Care should be the following:

A. For those of the present 330 million Americans that are not yet infected (immunologically naïve to the disease – COVID-19 negative), they should all be encouraged to receive one of the COVID-19 vaccines.

B. Every American who has had COVID-19 and is recovered by at least 14 days should be encouraged to donate COVID-19 Convalescent Plasma. <https://www.aabb.org/for-donors-patients/give-blood>

C. Every American who turns COVID-19 positive or becomes symptomatic (even if they have received a COVID-19 vaccine), should be afforded some form of **Passive Immunization** by the early-in-disease treatment COVID-19 Convalescent Plasma/Sera or Monoclonal Antibodies

D. As the COVID-19 mutations spread and the vaccines may be less effective, every American who turns COVID-19 positive or becomes symptomatic should be afforded **Passive Immunization** of COVID-19 Convalescent Plasma/Sera matching the COVID-19 mutation. Waiting for the development of a vaccine (or monoclonal antibodies) specific for the new COVID-19 mutation and withholding mutation specific COVID-19 Convalescent Plasma would be unconceivable and tantamount to patient

abandonment. Every time the coronavirus mutates, it will take months to develop a new vaccine or a new monoclonal antibody—yet convalescent plasma effective against every next mutation will be available 14 days after the first human recovers from each new mutation of the coronavirus through plasmapheresis donation.

E. When Kidney Transplantation was considered *Investigational* in the 1960s and 1970s and the insurance industry would not pay for Kidney Transplantation as it was “Experimental”, the Congress permitted for two decades the Attending Surgeons of Washington University SOM (Drs. Newton and Anderson) and Saint Louis University SOM (Drs. Maginn, Codd, and Garvin) to perform kidney transplants on both Veterans and civilians at the John Cochran (St. Louis) VAMC. Thus, the precedent six decades ago was set to employ the largest federal hospital system (both hospitals and CBOCs) in the nation of the Veterans Health Administration (VHA) to establish infusion centers to provide ***Passive Immunization*** in the treatment of COVID-19 for both Veterans and civilians.

F. Thomas Jefferson’s replacement of John Locke’s “property” with “the pursuit of happiness” in the *Declaration of Independence* was no mistake. We as American physicians should be leery of any potential inherent conflict-of-interest of *Industry’s* and *Medicine’s* working together possibly to the detriment of our patients. *De facto*, Medicine, the U.S. Government, and most of the World have publicly discredited polyclonal COVID-19 Convalescent Plasma (and Sera) while elevating monoclonal antibodies as viable early treatments in COVID-19 positivity—they are both ***Passive Immunization*** therapies. Every time the coronavirus mutates, it will take months to develop a new vaccine or a new monoclonal antibody—yet convalescent plasma effective against every next mutation will be available 14 days after the first human recovers from each new mutation of the coronavirus through plasmapheresis donation. The present situation throughout the World today is analogous to that of the mythological Sisyphus pushing the rock up the hill only for it upon nearing the top of the hill rolling back down for eternity.

After having viewed the abridged version of your interview on January 24, 2020 ([Full interview: Dr. Deborah Birx on "Face the Nation" - YouTube](#)) with Margaret Brennan, in my eyes you have throughout your professional life been a dedicated Military and Civil Service physician for individual patients and patients in the aggregate. Both you and I are professionally of the same generation. When we graduated, you from Penn State Univ SOM in 1980 and I in 1979 from Saint Louis Univ SOM, we both swore *Primum non Nocere* in the care of all of our patients throughout our future lives as physicians. As I viewed the interview last Sunday, I saw a physician who loves her country and has dedicated her life as a physician to bettering all patients’ lives. It is

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your duty, my duty, and all physicians' duty by our oaths of *Primum non Nocere* to advocate for not just the preventative measures of **Active Immunization** but also all potential therapeutic measures of **Passive Immunization**.

It would be my hope that this correspondence will be your introduction to President Biden to explain your suggestions and thoughts on our future therapy—**both Active Immunization and Passive Immunization**-- for all Americans. As Dr. Fauci is the President's Chief Medical Advisor on the USA COVID-19 epidemic, I will forward this letter to him, the NIH, and the FDA to help facilitate your meeting with the President. My previous Letter to the Editor of *The New England Journal of Medicine* has not been published but was probably partially the impetus for the *NEJM* publishing on January 6, 2021-01-06: Libster R, et al: [Early High-Titer Plasma Therapy to Prevent Severe Covid-19 in Older Adults \(nejm.org\)](https://www.nejm.org/doi/full/10.1056/NEJMe2020354) I will be sure to include the Editors of the *New England Journal of Medicine* in this correspondence today. Over the past year, I have submitted three items (listed below) to the U.S. Copyright Office of the Library of Congress to preserve the chronology of what has occurred for history. With any and all of my correspondence regarding our present COVID-19 epidemic, I will dutifully provide all that is asked of me by the U.S. Federal Government as it is my duty as a physician and surgeon of the Veterans Health Administration, U.S. Department of Veterans Affairs.

1. Andrus CH: *Time: The Crucial Independent Variable of the COVID-19 Pandemic*. U.S. Copyright Office, June 8, 2020. TXu002199029
2. Andrus CH: Mayo Clinic "Safety Update" should be Classified as a Completed Phase I Trial of COVID-19 Convalescent Plasma. July 22, 2020. TXu002214049
3. Andrus CH: 1 Dear Mr. President PLEASE COVID-19 Convalescent Plasma NOW 11-17-2020. November 18, 2020. TXu002232947

On the evening of January 20, 2021, the America public was reminded of past Presidential inaugural addresses:

President Abraham Lincoln's 2<sup>nd</sup> Inaugural Address includes the lines that I, as a VA physician and surgeon, and we as Americans have promised:

With malice toward none; with charity for all; with firmness in the right, as God gives us to see the right, let us strive on to finish the work we are in; to bind up the nation's wounds; **to care for him who shall have borne the battle, and for his widow, and his orphan**; to do all which may achieve and cherish a just, and a lasting peace, among ourselves, and with all nations.

That night, the most famous line of President Kennedy's was part of what was recited: "And so, my fellow Americans: ask not what your country can do for you—ask what you can do for your country." Dr. Birx, both you and I were in grammar school when the final lines were spoken that are most *apropos* to our present crisis and that for all time:

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My fellow citizens of the world: ask not what America will do for you, but what together we can do for the freedom of man.

Finally, whether you are citizens of America or citizens of the world, ask of us here the same high standards of strength and sacrifice which we ask of you. With a good conscience our only sure reward, with history the final judge of our deeds, let us go forth to lead the land we love, asking His blessing and His help, but knowing that here on earth God's work must truly be our own.

Dr. Birx: Godspeed.

Respectfully,

Charles H. Andrus, M.D., F.A.C.S.

Professor, Department of Surgery, Saint Louis University School of Medicine  
Chief, Unit II General Surgery (SLU GS division), St. Louis (John Cochran division)  
VAMC

Home: 314-455-9482; home e-mail: candrus600@aol.com

Beeper: 314-491-2417

My wife's, Pamela Bergkamp Andrus's, cell phone: 314-809-9634

- 739) 2021-02-02 U.S. Food & Drug Administration: CLINICAL MEMORANDUM, EUA 26382, COVID-19 Convalescent Plasma (CCP). **NONE OF THE VERSIONS OF THESE MEMOs are dated and thus dating was obtained from the digital captures using the Internet Archive (WayBack Machine).** The URL of this Memorandum is:  
<https://www.fda.gov/media/141480/download>

**From September 1, 2020 to at least February 2, 2021 was the first iteration/rough draft** to justify Hinton's reissuing the CCP EUA in November 2020 and then probably (the Wayback Machine has no digital captures from Feb 2 to Feb 15) the first major revision on February 4, 2021, of the CCP EUA of August 23, 2020 which was the first EUA regarding COVID-19 Convalescent Plasma issued by the FDA after the press conference announcement by President Trump of that day: Sunday, August 23, 2020—the day prior to the start of the Republican National Convention. Coincidentally, this **six-month draft** was the CLINICAL MEMORANDUM probably used to justify RADM Hinton's EUA of February 4, 2021 which was 48-72 hours after Dr. Andrus' Letter to Dr. Deborah Birx of February 1, 2021. As this first iteration of the MEMO regarding EUA 26382 was a draft, it lacks (1) the name of the individual who wrote it; (2) the name of the individual to whom it is written; and (3) the names of the FDA division chiefs through which the memo would pass. It does list the Sponsor, Robert Kadlec, M.D., to whom all EUAs previously have been issued regarding Remdesivir, Monoclonal Antibodies/Antibody Cocktails, and COVID-19 Convalescent Plasma (CCP).

<https://web.archive.org/web/20210202143902/https://www.fda.gov/media/141480/download>

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[oad](#) The Executive Summary of the CLINICAL MEMORANDUM of September 1, 2020 through at least February 2, 2021:

EXECUTIVE SUMMARY COVID-19 Convalescent Plasma (CCP), an unapproved biological product, is proposed for use under an Emergency Use Authorization (EUA) under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act), (21 USC 360bbb-3) as a passive immune therapy for the treatment of hospitalized patients with COVID-19, a serious or life-threatening disease. There currently is no adequate, approved, and available alternative to CCP for treating COVID-19. The sponsor has pointed to four lines of evidence to support that CCP may be effective in the treatment of hospitalized patients with COVID-19: 1) History of convalescent plasma for respiratory coronaviruses; 2) Evidence of preclinical safety and efficacy in animal models; 3) Published studies of the safety and efficacy of CCP; and 4) Data on safety and efficacy from the National Expanded Access Treatment Protocol (EAP) sponsored by the Mayo Clinic.

Considering the totality of the scientific evidence presented in the EUA, I conclude that current data for the use of CCP in adult hospitalized patients with COVID-19 supports the conclusion that CCP meets the “may be effective” criterion for issuance of an EUA from section 564(c)(2)(A) of the Act. It is reasonable to conclude that the known and potential benefits of CCP outweigh the known and potential risks of CCP for the proposed EUA. Current data suggest the largest clinical benefit is associated with high-titer units of CCP administered early in the course of disease. Adequate and well-controlled randomized trials remain necessary for a definitive demonstration of CCP efficacy and to determine the optimal product attributes and appropriate patient populations for its use.

**Recommendation:** CCP meets the eligibility criteria for EUA under section 564 of the Act.

**February 15, 2021 was the first digital capture of the second iteration** to justify the ongoing EUAs of COVID-19 Convalescent Plasma (CCP) upgrades by RADM Hinton. As this second iteration of the MEMO regarding EUA 26382 does not seem to be a draft, it contains (1) the name of the individual who wrote it; (2) the name of the individual to whom it is written; and (3) the names of the FDA divisions chiefs through which the memo would pass. It does not list the Sponsor (not yet appointed by the Biden administration and confirmed) to whom all EUAs will be issued regarding Remdesivir, Monoclonal Antibodies/Antibody Cocktails, and COVID-19 Convalescent Plasma (CCP).

<http://web.archive.org/web/20210215192634/https://www.fda.gov/media/141480/download>

[ad](#) The Executive Summary of the CLINICAL MEMORANDUM from February 15, 2021 to at least April 23, 2021 (the last digital capture by the WayBack Machine) to be unchanged:

## EXECUTIVE SUMMARY

COVID-19 Convalescent Plasma (CCP) was granted Emergency Use Authorization (EUA) for the treatment of hospitalized patients with COVID-19 on August 23, 2020. At that time, the totality of the scientific evidence supported a determination that the use of CCP in hospitalized patients with COVID-19 met the “may be effective” standard for issuance of an EUA, and it was reasonable to consider that the known and potential benefits of CCP outweighed the known and potential risks for the authorized use.

Following the EUA, emerging evidence from randomized controlled trials has continued to inform this assessment. The available evidence indicates that 1) the use of low titer CCP in hospitalized patients no longer meets the evidentiary standard of “may be effective”, and 2) high titer CCP has not demonstrated benefit when administered late in the disease course in immunocompetent hospitalized patients.

Additional data from RCTs and observational studies support a determination that high titer CCP may be effective when administered early in the course of illness, particularly prior to the expected time of host antibody response. In patients with impaired humoral immunity, the potential therapeutic window may be prolonged. As RCT data continue to demonstrate that the risks of CCP do not exceed those observed with plasma transfusion in general, it is reasonable to believe that the known and potential benefits of use of high titer CCP outweigh the known and potential risks when used for the treatment of hospitalized patients with COVID-19, particularly early in the course of illness or in patients with impaired humoral immunity. Results from ongoing RCTs are expected to continue inform the optimal patient populations and product characteristics for efficacy of CCP in COVID-19.

**Recommendation:** *The conditions of Emergency Use Authorization for CCP for the treatment of hospitalized patients with COVID-19 should be revised to exclude the use of low titer CCP. High titer CCP continues to meet criteria for Emergency Use Authorization for the treatment of hospitalized patients with COVID-19 early in the course of hospitalization.* The letter of authorization and accompanying fact sheets should be revised to emphasize early administration of CCP in the absence of immunodeficiency or immunosuppression. Additional results from adequate and well-controlled trials will continue to be evaluated to further characterize the patient populations and product characteristics meeting EUA criteria.

- 740)** 2021-02-04 Hinton DM: U.S. Food and Drug Administration Letter to Nikki Bratcher-Bowman, Acting Assistant Secretary for Preparedness and Response, EUA-update regarding COVID-19 Convalescent plasma. February 4, 2021. (Please note that the position of Assistant Secretary of Preparedness and Response changed from February 2, 2021 (48 hours previous) from Robert Kadlec, M.D. who had been appointed by President Trump to an Acting Assistant Secretary for Preparedness and Response under the Biden Administration: Nikki Bratcher-Bowman.)

<https://web.archive.org/web/20210218201225/https://www.fda.gov/media/141477/download>

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3), the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19 (the virus was later named SARS-CoV-2).<sup>1</sup> On March 27, 2020, on the basis of such determination, the Secretary of HHS declared that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic, pursuant to Section 564 of the Act, subject to the terms of any authorization issued under that section.<sup>2</sup> On August 23, 2020, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for the emergency use of COVID-19 convalescent plasma for the treatment of hospitalized patients with Coronavirus Disease 2019 (COVID-19), pursuant to Section 564 of the Act.<sup>3</sup> On November 30, 2020, FDA reissued the August 23, 2020, Letter of Authorization to add a test acceptable to be used in the manufacture of COVID-19 convalescent plasma.<sup>4</sup> Having concluded that revising this EUA is appropriate to protect the public health or safety under Section 564(g)(2)(C) of the Act (21 U.S.C. § 360bbb-3(g)(2)(C)), **FDA is again reissuing the Letter of Authorization in its entirety with revisions**

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to: (1) include updates based on data from additional clinical trials; **(2) clarify that the authorization is limited to use of only high titer COVID-19 convalescent plasma in hospitalized patients early in the course of disease and those hospitalized with impaired humoral immunity;** (3) add the Abbott SARS-CoV-2 IgG test (ARCHITECT and Alinity i platforms), Beckman Coulter Access SARS-CoV-2 IgG test, EUROIMMUN Anti-SARS-CoV-2 ELISA (IgG) test, GenScript cPass SARS-CoV-2 Neutralization Antibody Detection Kit test, Kantaro COVID-SeroKlir test, Roche Elecsys AntiSARS-CoV-2 S test, and Siemens ADVIA Centaur SARS-CoV-2 IgG (COV2G) test as acceptable tests to be used for the purpose of qualifying high titer COVID-19 convalescent plasma in the manufacture of COVID-19 convalescent plasma; and (4) change the cutoff of the Ortho VITROS Anti-SARS-CoV-2 IgG test from  $S/C \geq 12.0$  to  $S/C \geq 9.5$  for qualification of COVID-19 convalescent plasma as high titer. COVID-19 convalescent plasma is human plasma collected from individuals whose plasma contains anti-SARS-CoV-2 antibodies, and who meet all donor eligibility requirements (21 CFR 630.10 and 21 CFR 630.15) and qualifications. It is an investigational product and is not currently approved or licensed for any indication. The initial issuance of this EUA for COVID-19 convalescent plasma was based on review of historical evidence using convalescent plasma in prior outbreaks of respiratory viruses, certain preclinical evidence, results from small clinical trials of convalescent plasma conducted during the current outbreak, and data obtained from the National Convalescent Plasma Expanded Access Protocol (EAP) sponsored by the Mayo Clinic.<sup>5</sup> Following the August 23, 2020 authorization, additional studies, including randomized, controlled trials, have provided data to further inform the safety and efficacy of COVID-19 convalescent plasma, and further characterize product attributes and patient populations for its use. Based on assessment of these data, potential clinical benefit of transfusion of COVID-19 convalescent plasma in hospitalized patients with COVID-19 is associated with high titer units administered early in the course of disease.<sup>6</sup> Transfusion of COVID-19 convalescent plasma in hospitalized patients late in the course of illness (e.g., following respiratory failure requiring intubation and mechanical ventilation) has not been associated with clinical benefit. These considerations may be different in patients with suppressed or deficient humoral immunity. **Therefore, this EUA is being revised to authorize only the use of high titer COVID-19 convalescent plasma, for the treatment of hospitalized patients with COVID-19, early in the disease course.** The related fact sheets are revised accordingly. The use of low titer COVID-19 convalescent plasma is no longer authorized under this EUA.

It is reasonable to believe that the known and potential benefits of high titer COVID-19 convalescent plasma outweigh its known and potential risks for the treatment of patients hospitalized with COVID-19 early in the disease course.<sup>7</sup> COVID-19 convalescent plasma should not be considered a new standard of care for the treatment of patients with COVID-19. Given that the clinical evidence supporting this EUA remains limited, data from additional randomized, controlled trials are needed. Ongoing clinical trials of COVID-19 convalescent plasma should not be amended based on the issuance of this updated EUA; providers are encouraged to enroll patients in those trials. Having concluded that the criteria for issuance of this authorization under 564(c) of the Act are met, I am authorizing the emergency use of high titer COVID-19 convalescent plasma for treatment of hospitalized patients with COVID-19, as described in the Scope of Authorization section of this letter (Section II) and subject to the terms of this authorization.

- 741) 2021-02-04 U.S. Food & Drug Administration: FDA in Brief: FDA Updates Emergency Use Authorization for COVID-19 Convalescent Plasma to Reflect New Data, February 4, 2021. This is deliberate legal obfuscation on the part of the FDA by stating that it was limiting authorization-- *de facto*, the FDA was really expanding authorization by appropriately limiting the EUA for COVID-19 Convalescent Plasma to "early in the disease course" which was contrary to FDA directives from March 24, 2020 to**

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September 2, 2020 when the criteria was that CCP could *only* be given to severe patients late in the disease course. The provision of CCP late in the disease course was *de facto* perpetuated by the fact that the FDA had unobtrusively removed the strict severity of illness criteria late in the disease course from all FDA documentation by overwriting on September 2, 2020 and going forward on all subsequent documentation and not announcing it *officially* to the U.S. Medical and Research Community, probably the rest of the Federal Government, and most definitely not to the American people. The “high dose” vs “low dose” concern is a secondary issue—that was used as a distraction by the FDA—as with monoclonal antibodies/antibody cocktails, COVID-19 Convalescent Plasma and monoclonal antibodies are all *Passive Immunization* and are therapeutically identical if given EARLY IN THE COURSE OF THE DISEASE. <https://www.fda.gov/news-events/fda-brief/fda-brief-fda-updates-emergency-use-authorization-covid-19-convalescent-plasma-reflect-new-data>

The following quote is attributed to **Peter Marks, M.D., Ph.D., Director of FDA’s Center for Biologics Evaluation and Research:**

“The FDA is issuing a revision of the Emergency Use Authorization (EUA) for COVID-19 convalescent plasma as a result of our evaluation of the most recent information available. Based upon data from new clinical trials analyzed or reported since the original EUA was issued in August 2020, we have revised the EUA to limit the authorization to the use of high titer COVID-19 convalescent plasma for the treatment of hospitalized patients early in the disease course. This and other changes to the EUA represent important updates to the use of convalescent plasma for the treatment of COVID-19 patients.

“Issuance of, and updates to, EUAs are based on a thorough evaluation of currently available scientific evidence about medical products. In this case, as additional scientific evidence about COVID-19 convalescent plasma emerged, we revised the EUA to reflect the updated evidence. COVID-19 convalescent plasma used according to the revised EUA may have efficacy and its known and potential benefits outweigh its known and potential risks.”

- 742) 2021-02-04. Cox D: The vaccine alternatives for people with compromised immune systems. National Geographic Science – Coronavirus. February 4, 2021. <https://www.nationalgeographic.com/science/article/the-vaccine-alternatives-for-people-with-compromised-immune-systems>
- 743) 2021-02-04 Roxby P: Covid: ‘Convalescent plasma no benefit to hospital patients.’ British Broadcasting Corporation (BBC) <https://www.bbc.com/news/health-55681051>
- 744) 2021-02-05 REGENERON: Regeneron reports fourth quarter and full year 2020 financial and operating results. <https://investor.regeneron.com/news-releases/news-release-details/regeneron-reports-fourth-quarter-and-full-year-2020-financial>

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745) 2021-02-05 Yoon D: Enthusiasm fades for Covid-19 antibody treatments in South Korea – ‘We are hoping the treatment will lighten the burden of hospitalizing patients with serious symptoms’. The Wall Street Journal, Feb. 5, 2021 7:02 am ET.  
<https://www.wsj.com/articles/enthusiasm-fades-for-covid-19-antibody-treatments-in-south-korea-11612526555>

746) 2021-02-05 Dockser Marcus A: FDA Limits Use of Convalescent Plasma as Covid-19 Treatment. Agency to scale back authorization of the antibody-rich blood component after studies yielded mixed results. The Wall Street Journal Feb 5, 2021.  
<https://www.wsj.com/articles/fda-limits-use-of-convalescent-plasma-as-covid-19-treatment-11612537239>

***[This article is copied verbatim from the Wall Street Journal with annotations so as to translate what is meaningfully being said by those interviewed!].***

The Food and Drug Administration [is scaling back its authorization](#) of the use of convalescent blood-plasma for Covid-19 patients in an effort to guide physicians who have faced a confusing thicket of data about the therapy’s effectiveness.

The agency said late Thursday that the authorization, [a subject of controversy since it was first issued last August](#), would be revised to limit the use of plasma to [hospitalized patients early in the course of the disease](#) and [hospitalized patients with a medical condition that impairs their ability to make antibodies](#). Patients will be allowed to receive [only plasma containing high concentrations of antibodies](#).

“The update is meant so convalescent plasma can best be used on those who will benefit,” said Peter Marks, director of the FDA’s Center for Biologics Evaluation and Research. “It is being used somewhat more indiscriminately.” ***[High-titer COVID-19 Convalescent Plasma should be given to everyone becoming COVID-19 positive within <72 hours. – NOT just those hospitalized.—C. Andrus]***

Dr. Claudia Cohn, chief medical officer of AABB, an organization representing the transfusion-medicine community, said the group plans to issue interim recommendations on convalescent plasma later this month. “There are so many studies coming out with different conclusions,” she said. “It is not clean, it is not black and white.”

Dr. Marks said the FDA reached its decision after evaluating results from several recent studies. Some showed benefits from convalescent plasma, the antibody-containing fluid derived from the blood of people who have recovered from Covid-19. Others showed no benefit.

Two clinical trials of convalescent plasma for hospitalized patients shut down last month after investigators said there appeared to be no benefit. Three trials involving hospitalized patients recently reported some benefit for the plasma, but only when given to patients soon after admission. ***Still another trial showed that elderly outpatients given plasma shortly after showing symptoms were less likely to develop serious disease. ---- [This was the January 6, 2021 publication in The New England Journal of***

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**Treatment:** Passive Immunization: COVID-19 Convalescent Plasma and Antibodies and Antivirals  
**Prevention:** Active Immunization: Vaccines

***Medicine which is the ONLY Prospective randomized, placebo controlled trial of CCP administration in one cohesive age group (~70 years of age). THIS IS A LANDMARK STUDY! – C. Andrus]***

Arturo Casadevall, chair of molecular microbiology and immunology at the Johns Hopkins Bloomberg School of Public Health, called the FDA decision “a step forward.” He said, “Physicians in the U.S. for the first time are going to have guidance on when to use it and how to use” convalescent plasma.

Dr. Casadevall is a co-founder of the Covid-19 Convalescent Plasma Project, which helped [organize a nationwide expanded-access study of convalescent plasma](#) that began last April.

Despite the contradictory findings, convalescent plasma remains in demand—in part because there are few effective treatments for Covid-19 and many people remain unvaccinated. Since the FDA issued the emergency authorization last August, the blood industry has distributed on average about 20,600 units of convalescent plasma a week to hospitals around the country, according to the American Red Cross.

The FDA’s earlier decision to authorize [convalescent plasma for hospitalized Covid-19 patients](#) was based in large part on results from an agency-sponsored [expanded-access program](#), through which more than 72,000 patients received plasma. For a study published last month in the New England Journal of Medicine, researchers analyzed data from 3,000 of those patients and reported an apparent survival benefit among hospitalized patients not on mechanical ventilation who received plasma containing high concentrations of antibodies.

But many scientists expressed skepticism about that finding, saying expanded-access studies lack the scientific rigor of traditional trials because they have no control group to compare any apparent effect.

**The FDA’s Dr. Marks said the authorization of convalescent plasma “could have been handled much better. It had to do with the sense of urgency everyone is feeling. I can’t blame anyone for feeling a sense of urgency.” -- [As Dr. Marks is the Director of the FDA’s CBER (Center for Biologics Evaluation and Research), it was his sole responsibility to have handled it better from March 2020 to the present for the biologic: COVID-19 Convalescent Plasma which is a biosimilar biologic to rabies vaccine, gamma globulin, RhoGam, hypertet, small pox convalescent plasma, IVIG, FFP, etc., etc., etc!]**

Dr. Marks also said the data could be confusing. Each unit of convalescent plasma is unique, reflecting the immune response of the recovered patient who donated it. It took time to figure out the best way to measure the antibodies in a unit, he added.

The U.S. isn’t the only government trying to establish reliable guidelines on the use of convalescent plasma. In Argentina, a study in elderly outpatients published last month in the New England Journal of Medicine contributed to current recommendations there to treat elderly Covid-19 patients early in the course of their illness. “Plasma supplies are not endless, and invariably public health officials face difficult decisions,” said study co-author Dr. Fernando Polack of

Fundación Infant in Buenos Aires. “In any of these decisions, guidelines based on data are necessary and are the best way for clinicians to feel comfortable when facing individual cases.”

**Louis M. Katz**, chief medical officer of Mississippi Valley Regional Blood Center in Davenport, Iowa, which provides blood products for over 120 hospitals, said the evidence supporting the use of convalescent plasma in hospitalized patients is weak. **“I think the data is there that it works early,”** he said. **“As you move into sicker and sicker people, the evidence gets thinner and thinner.”**

In an editorial that accompanied the New England Journal of Medicine paper on the U.S. expanded-access study, **Dr. Katz said convalescent plasma should be used only in patients early in the course of the disease**. The problem with that suggestion, he later added, is the FDA emergency-use authorization still covers only hospitalized patients, who tend to show up at the hospital when they have been sick for a longer time. **– [This is the problem, to become hospitalized, most patients have to be very sick and thus outside the <72 hour window! – C. Andrus, M.D.]**

Treating Covid-19 patients who are just starting to show symptoms poses its own challenges. “Logistically, it is very difficult to treat patients earlier,” Dr. Katz said. **“It’s hard to transfuse lots of plasma in outpatients.” [BUT IT CAN BE DOWN IN INFUSION CENTERS or Hospital outpatient centers as is done for all infusion chemotherapies, chronic blood transfusions, etc! – C. Andrus. M.D.]**

Dr. Marks said a large National Institutes of Health study is now under way to test convalescent plasma in people with Covid-19 who are sick enough to come to the emergency room but aren’t admitted to the hospital, as are other randomized controlled trials of plasma in outpatients. “Until we have those data, we are going to keep the authorization to hospitalized patients,” he said. **“We will refine it again if appropriate. This is a scarce resource.” [High-titer COVID-19 Convalescent Plasma should NOT be a scarce resource as it can be obtained twice a week from the same convalescent donor by PLASMAPHORESIS and the product from each donation will yield 2 doses (4 doses per week) and it can be stored as FFP (Fresh Frozen Plasma) for at least a year! In short, there are over 5,000 blood banks in the US so if each Blood Bank processed 20 units a day of COVID-19 Convalescent Plasma, that would be:**

**20 donations / day times 7 days/week times >5000 U.S. Blood Banks times 2 doses of CCP / donation = greater than 1.4 million doses per week of CCP**  
**– C. Andrus, M.D.]**

Write to Amy Dockser Marcus at [amy.marcus@wsj.com](mailto:amy.marcus@wsj.com)  
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*Appeared in the February 6, 2021, print edition as 'FDA Limits Plasma as Treatment.'*

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**Treatment:** Passive Immunization: COVID-19 Convalescent Plasma and Antibodies and Antivirals  
**Prevention:** Active Immunization: Vaccines

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- 756) 2021-02-10 **Andrus C**: Use of COVID-19 convalescent plasma EARLY in the course of the disease. ResearchGate [https://www.researchgate.net/post/Use\\_of\\_COVID-19\\_Convalescent\\_Plasma\\_EARLY\\_in\\_the\\_course\\_of\\_the\\_disease](https://www.researchgate.net/post/Use_of_COVID-19_Convalescent_Plasma_EARLY_in_the_course_of_the_disease)
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<http://web.archive.org/web/20210416100402/https://www.covid19treatmentguidelines.nih.gov/therapeutic-management/>

These is verbatim from the February 11, 2021, NIH Recommendations.

### Executive Summary

Two main processes are thought to drive the pathogenesis of COVID-19. Early in the course of the infection, the disease is primarily driven by replication of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Later in the course of infection, the disease is driven by an exaggerated immune/inflammatory response to the virus that leads to tissue damage. Based on this understanding, it is anticipated that antiviral therapies would have the greatest effect early in the course of disease, while immunosuppressive/anti-inflammatory therapies are likely to be more beneficial in the later stages of COVID-19.

In the earliest stages of infection, before the host has mounted an effective immune response, anti-SARS-CoV-2 antibody-based therapies may have their greatest likelihood of having an effect. In this regard, although there are insufficient data from clinical trials to recommend either for or against the use of any specific therapy in this setting, preliminary data suggests that outpatients may benefit from receiving anti-SARS-CoV-2 monoclonal antibodies early in the course of infection. The Food and Drug Administration (FDA) has issued Emergency Use Authorizations (EUAs) for certain anti-SARS-CoV-2 monoclonal antibodies for the treatment of outpatients with mild to moderate COVID-19; please see [Anti-SARS-CoV-2 Monoclonal Antibodies](#) for more information.

Remdesivir, an antiviral agent, is currently the only drug that is approved by the FDA for the treatment of COVID-19. It is recommended for use in hospitalized patients who require supplemental oxygen. However, it is not routinely recommended for patients who require mechanical ventilation due to the lack of data showing benefit at this advanced stage of the disease.<sup>1-4</sup>

Dexamethasone, a corticosteroid, has been found to improve survival in hospitalized patients who require supplemental oxygen, with the greatest effect observed in patients who require mechanical ventilation. Therefore, the use of dexamethasone is strongly recommended in this setting.<sup>5-8</sup>



The COVID-19 Treatment Guidelines Panel (the Panel) continues to review the most recent clinical data to provide up-to-date treatment recommendations for clinicians who are caring for patients with COVID-19. Figure 1 summarizes the Panel's recommendations for managing patients with varying severities of disease.

**Figure 1. Pharmacologic Management of Patients with COVID-19 Based on Disease Severity**

Doses and durations are listed in the footnote.

DISEASE SEVERITY	PANEL'S RECOMMENDATIONS
Not Hospitalized, Mild to Moderate COVID-19	There are insufficient data to recommend either for or against any specific antiviral or antibody therapy. SARS-CoV-2 neutralizing antibodies (bamlanivimab or casirivimab plus imdevimab) are available through EUAs for outpatients who are at high risk of disease progression. <sup>a</sup>  The Panel recommends against the use of <b>dexamethasone</b> or <b>other corticosteroids (AIII)</b> . <sup>b</sup>
Hospitalized but Does Not Require Supplemental Oxygen	The Panel recommends against the use of <b>dexamethasone (AIIa)</b> or <b>other corticosteroids (AIII)</b> . <sup>b</sup>  There are insufficient data to recommend either for or against the routine use of remdesivir. For patients at high risk of disease progression, the use of remdesivir may be appropriate.
Hospitalized and Requires Supplemental Oxygen (But Does Not Require Oxygen Delivery Through a High-Flow Device, Noninvasive Ventilation, Invasive Mechanical Ventilation, or ECMO)	Use one of the following options: <ul style="list-style-type: none"> <li>• <b>Remdesivir<sup>c,d</sup></b> (e.g., for patients who require minimal supplemental oxygen) (<b>BIIa</b>)</li> <li>• <b>Dexamethasone<sup>e</sup> plus remdesivir<sup>c,d</sup></b> (e.g., for patients who require increasing amounts of supplemental oxygen) (<b>BIII</b>)<sup>f,g</sup></li> <li>• <b>Dexamethasone<sup>e</sup></b> (e.g., when combination therapy with remdesivir cannot be used or is not available) (<b>BI</b>)</li> </ul>
Hospitalized and Requires Oxygen Delivery Through a High-Flow Device or Noninvasive Ventilation	Use one of the following options: <ul style="list-style-type: none"> <li>• <b>Dexamethasone<sup>e,g</sup> (AI)</b></li> <li>• <b>Dexamethasone<sup>e</sup> plus remdesivir<sup>c,d</sup> (BIII)</b><sup>f,g</sup></li> </ul>
Hospitalized and Requires Invasive Mechanical Ventilation or ECMO	<b>Dexamethasone<sup>e</sup> (AI)</b> <sup>h</sup>
<b>Rating of Recommendations:</b> A = Strong; B = Moderate; C = Optional <b>Rating of Evidence:</b> I = One or more randomized trials without major limitations; IIa = Other randomized trials or subgroup analyses of randomized trials; IIb = Nonrandomized trials or observational cohort studies; III = Expert opinion	

<sup>a</sup> See the Anti-SARS-CoV-2 Monoclonal Antibodies section for more information on using bamlanivimab and casirivimab plus imdevimab in patients with mild to moderate COVID-19.

<sup>b</sup> Patients who are receiving corticosteroids for other indications should continue therapy for their underlying conditions as directed by their health care providers.

<sup>c</sup> The remdesivir dose is 200 mg IV for one dose, followed by remdesivir 100 mg IV once daily for 4 days or until hospital discharge (unless the patient is in a health care setting that can provide acute care that is similar to inpatient hospital care). Treatment duration may be extended to up to 10 days if there is no substantial clinical improvement by Day 5.

<sup>d</sup> For patients who are receiving remdesivir but progress to requiring oxygen through a high-flow device, noninvasive ventilation, invasive mechanical ventilation, or ECMO, remdesivir should be continued until the treatment course is completed.

<sup>e</sup> The dexamethasone dose is 6 mg IV or PO once daily for 10 days or until hospital discharge. If dexamethasone is not available, equivalent doses of other corticosteroids (e.g., prednisone, methylprednisolone, hydrocortisone) may be used. See the Corticosteroids section for more information.

<sup>f</sup> The combination of dexamethasone and remdesivir has not been studied in clinical trials.

<sup>g</sup> In the rare circumstances where corticosteroids cannot be used, **baricitinib plus remdesivir** can be used (**BIIa**). The FDA has issued an EUA for baricitinib use in combination with remdesivir. The dose for baricitinib is 4 mg PO once daily for 14 days or until hospital discharge.

<sup>h</sup> The combination of **dexamethasone and remdesivir** may be considered for patients who have recently been intubated (**CIII**). The Panel **recommends against** the use of remdesivir monotherapy in these patients.

**Key:** ECMO = extracorporeal membrane oxygenation; EUA = Emergency Use Authorization; FDA = Food and Drug Administration; IV = intravenous; the Panel = the COVID-19 Treatment Guidelines Panel; PO = orally; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2

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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and Antivirals

**Prevention:** *Active Immunization:* Vaccines

- 759)** 2021-02-11 U.S. Food & Drug Administration: Investigational COVID-19 convalescent plasma – Guidance for Industry. February 11, 2021 supersedes that issued January 15, 2021. <https://web.archive.org/web/20210405090328/https://www.fda.gov/media/136798/download>

On August 23, 2020, FDA issued an EUA for COVID-19 convalescent plasma for the treatment of hospitalized patients with COVID-19. FDA has subsequently reissued the EUA with revisions. However, adequate and well-controlled randomized trials remain necessary for a definitive demonstration of COVID-19 convalescent plasma efficacy and to determine the optimal product attributes and appropriate patient populations for its use. Additional data will be forthcoming from other analyses and ongoing, well-controlled clinical trials. The ongoing clinical trials of investigational convalescent plasma should not be amended based on the issuance of the EUA; health care providers are encouraged to enroll patients in those trials.

....

### III. RECOMMENDATIONS

#### A. Pathways for Use of Investigational Convalescent Plasma

Because convalescent plasma for the treatment of COVID-19 has not yet been approved for use by FDA, <sup>5</sup> it is regulated as an investigational product. As such, its administration must be under the EUA or an IND. The emergency use of COVID-19 convalescent plasma is not authorized under the EUA unless it is consistent with, and does not exceed, the terms of the Letter of Authorization, including the Scope of Authorization and Conditions of Authorization. <sup>6</sup> Alternatively, investigational convalescent plasma may be administered under the traditional IND regulatory pathway, a single-patient IND for emergency use, or an intermediate-size population expanded access IND (section 351(a)(3) of the PHS Act (42 U.S.C. 262(a)(3)); section 505(i) of the FD&C Act (21 U.S.C. 355(i)); 21 CFR 601.21; and 21 CFR Part 312).

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<sup>3</sup> Secretary of Health and Human Services, Determination that a Public Health Emergency Exists (originally issued Jan. 31, 2020, and subsequently renewed), available at <https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx>.

<sup>4</sup> Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) (Mar. 13, 2020), available at <https://trumpwhitehouse.archives.gov/presidential-actions/proclamation-declaring-nationalemergency-concerning-novel-coronavirus-disease-covid-19-outbreak/>.

<sup>5</sup> Convalescent plasma is a biological product subject to the licensure requirement under section 351 of the PHS Act. 42 U.S.C. 262(a). <sup>6</sup> See <https://www.fda.gov/media/141477/download>.....

FDA does not collect convalescent plasma or provide convalescent plasma. Health care providers or acute care facilities should obtain convalescent plasma from an FDA-registered or licensed blood establishment.

The following pathways are available for administering or studying the use of convalescent plasma:

#### 1. Emergency Use Authorization

On August 23, 2020, FDA issued an EUA for COVID-19 Convalescent Plasma for the treatment of hospitalized patients with COVID-19. FDA has subsequently reissued the EUA with revisions.

Health care providers intending to administer COVID-19 convalescent plasma under the EUA are not required to report its use to FDA. Providers should refer to the Fact Sheet for Health Care Providers<sup>7</sup> for information on the intended use and known and potential risks and benefits of COVID-19 convalescent plasma. The Fact Sheet also provides a description of the product, information on the dosage, administration and storage of COVID-19 convalescent plasma, use in specific populations, and instructions for communicating with recipients.

As described in the Fact Sheet, health care providers must maintain records and conduct a thorough investigation of adverse reactions after transfusion of COVID-19 convalescent plasma, and must report fatalities to FDA as required in 21 CFR 606.170. Refer to FDA's guidance entitled "Notifying FDA of Fatalities Related to Blood Collection or Transfusion" for recommendations on reporting fatalities related to blood transfusion to FDA (Ref. 8).

## 2. Clinical Trials

The EUA is not intended to replace clinical trials that are critically important for the definitive demonstration of safety and efficacy of investigational convalescent plasma. Ongoing clinical trials of investigational convalescent plasma should not be amended based on the issuance of the EUA. Health care providers are encouraged to enroll patients in those trials and complete clinical trials to fully answer the questions about the effectiveness of convalescent plasma for the treatment of COVID-19.

Investigators wishing to study the use of convalescent plasma in a clinical trial should submit requests to FDA for investigational use under the traditional IND regulatory pathway (21 CFR Part 312). The Center for Biologics Evaluation and Research (CBER) Office of Blood Research and Review (OBRR) is committed to engaging with sponsors and reviewing such requests expeditiously. During the COVID-19 pandemic, INDs may be submitted via email to [CBERDCC\\_eMailSub@fda.hhs.gov](mailto:CBERDCC_eMailSub@fda.hhs.gov).

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<sup>7</sup> See <https://www.fda.gov/media/141478/download>.

## Contains Nonbinding Recommendations

## 3. Expanded Access

An IND application for expanded access is an alternative for use of investigational convalescent plasma for patients with serious or immediately life-threatening COVID-19 disease who are not eligible or who are unable to participate in randomized clinical trials (21 CFR 312.305). During the COVID-19 pandemic, INDs for expanded access, that are not single patient INDs, may be submitted via email to [CBERDCC\\_eMailSub@fda.hhs.gov](mailto:CBERDCC_eMailSub@fda.hhs.gov).

### a. Single Patient IND for Emergency Use

Given the public health emergency that the COVID-19 pandemic presents, FDA is continuing to facilitate access to investigational convalescent plasma through the process of a physician requesting a single patient IND for an individual

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patient with serious or life-threatening COVID-19 under 21 CFR 312.310. This process allows the use of an investigational drug for the treatment of an individual patient by a licensed physician upon FDA authorization, if the applicable regulatory criteria are met. Note, in such cases, a licensed physician seeking to administer investigational convalescent plasma to an individual patient must request the IND (21 CFR 312.310(b)).

Note: Given that the intended use of COVID-19 convalescent plasma under the EUA is for treatment of hospitalized COVID-19 patients, FDA expects few requests for single patient INDs. FDA recommends that physicians seeking to use convalescent plasma for hospitalized COVID-19 patients should do so under the EUA and not under single patient INDs. Other options for the use of investigational convalescent plasma are listed above.

To obtain a single patient IND for emergency use, the requesting physician may contact FDA by completing **Form FDA 3926** (<https://www.fda.gov/media/98616/download>) and submitting the form by email to [CBER\\_eIND\\_Covid-19@FDA.HHS.gov](mailto:CBER_eIND_Covid-19@FDA.HHS.gov). CBER requests that all forms be filled out electronically to facilitate rapid review. Handwritten forms are often hard to read and may delay the processing of the request. For more detailed instructions see the Form FDA 3926 Instructions (<https://www.fda.gov/media/98627/download>).

For requests when the provider is unable to complete and submit **Form FDA 3926** due to extenuating circumstances, or in the case of a medical emergency between the hours of 8pm and 8am Eastern Time (ET), i.e., when authorization and issuance of an IND number is needed before 8am ET the next morning, the provider should contact FDA's Office of Emergency Operations at 1-866-300-4374 to be routed to the appropriate clinical review staff for assistance with submitting the request and issuance of an IND number. ....

- 760)** 2021-02-12 Karamyan VT: Between two storms, vasoactive peptides or bradykinin underlie severity of COVID-19? The Physiological Society, Physiological Reports REVIEW. 09 March 2021;9 (5):e14796, 1-9.  
<https://physoc.onlinelibrary.wiley.com/doi/10.14814/phy2.14796>

## Abstract

Coronavirus disease 2019 (COVID-19), caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), continues to be a world-wide pandemic with overwhelming socioeconomic impact. Since inflammation is one of the major causes of COVID-19 complications, the associated molecular mechanisms have been the focus of many studies to better understand this disease and develop improved treatments for patients contracting SARS-CoV-2. Among these, strong emphasis has been placed on pro-inflammatory cytokines, associating severity of COVID-19 with so-called "cytokine storm." More recently, peptide bradykinin, its dysregulated signaling or "bradykinin storm," has emerged as a primary mechanism to explain COVID-19-related complications. Unfortunately, this important development may not fully capture the main molecular players that underlie the disease severity. To this end, in this focused review, several lines of evidence are provided to suggest that in addition to bradykinin, two closely related vasoactive peptides, substance P and neurotensin, are also likely to drive microvascular

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permeability and inflammation, and be responsible for development of COVID-19 pathology. Furthermore, based on published experimental observations, it is postulated that in addition to ACE and neprilysin, peptidase neurolysin (Nln) is also likely to contribute to accumulation of bradykinin, substance P and neurotensin, and progression of the disease. In conclusion, it is proposed that “vasoactive peptide storm” may underlie severity of COVID-19 and that simultaneous inhibition of all three peptidergic systems could be therapeutically more advantageous rather than modulation of any single mechanism alone.

**761)** 2021-01-13 Fandos N: Trump acquitted of inciting insurrection, Even as bipartisan majority votes ‘Guilty’. The New York Times  
<https://www.nytimes.com/2021/02/13/us/politics/trump-impeachment.html>

**762)** 2021-02-13 **McConnell M**: Mitch McConnell Speech Transcript after vote to acquit Trump in 2<sup>nd</sup> impeachment trial. Rev <https://www.rev.com/blog/transcripts/mitch-mcconnell-speech-transcript-after-vote-to-acquit-trump-in-2nd-impeachment-trial>

Mitch McConnell: (00:00)  
Mr President.

Speaker 2: (00:01)  
The Republican leader.

Mitch McConnell: (00:04)  
January 6th was a disgrace. American citizens attacked their own government. They use terrorism to try to stop a specific piece of domestic business they did not like. Fellow Americans beat and bloodied our own police. They stormed the center floor. They tried to hunt down the Speaker of the House. They built a gallows and chatted about murdering the vice president. They did this because they’d been fed wild, falsehoods by the most powerful man on earth because he was angry. He lost an election. Former President Trump’s actions preceded the riot or a disgraceful dereliction of duty. The House accused the former president of quote “Incitement”. That is a specific term from the criminal law. Let me just put that aside for a moment and reiterate something I said weeks ago. There’s no question, none, that President Trump is practically and morally responsible for provoking the events of the day. No question about it.

Mitch McConnell: (01:46)  
The people who stormed this building believed they were acting on the wishes and instructions of their president and having that belief was a foreseeable consequence of the growing crescendo of false statements, conspiracy theories, and reckless hyperbole, which the defeated president kept shouting into the largest megaphone on planet Earth. The issue is not only the president in temperate language on January 6th. It is not just his endorsement of remarks in which an associate urged quote “Trial by combat”. It was also the entire manufactured atmosphere of looming catastrophe. The increasingly wild myths about a reverse landslide election that was somehow being stolen. Some secret coup by our now president.

Mitch McConnell: (03:09)  
Now I defended the president’s right to bring any complaints to our legal system. The legal system spoke, the electoral college spoke. As I stood up and said, clearly at that time, the election was settled. It was over, but that just really opened a new chapter of even wilder and more unfounded claims. The leader of the free world cannot spend weeks thundering that

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shadowy forces are stealing our country and then feign surprise when people believe him and do reckless things. I sadly many politicians sometimes make overheated comments or use metaphors. We saw that. That unhinged listeners might take literally, but that was different. That's different from what we saw. This was an intensifying crescendo of conspiracy theories orchestrated by an outgoing president who seemed determined to either overturn the voter's decision or else torch our institutions on the way out. The unconscionable behavior did not end when the violence actually began.

Mitch McConnell: (04:47)

Whatever our ex president claims he thought might happen a day, whatever right reaction he's says he meant to produce by that afternoon we know he was watching the same live television as the rest of us. A mob was assaulting the Capitol in his name, these criminals who are carrying his banners, hanging his flags and screaming their loyalty to him. It was obvious that only President Trump could end this. He was the only one who could. Former aides publicly begged him to do so. Loyal allies frantically called the administration. The president did not act swiftly. He did not do his job. He didn't take steps so federal law could be faithfully executed and order restored. No, instead, according to public reports, he watched television happily as the chaos unfolded. He kept pressing his scheme to overturn the election. Now, even after it was clear to any reasonable observer that Vice President Pence was in serious danger. Even as the mob carrying Trump banners was beating cops and breaching perimeters their president sent a further tweet, attacking his own vice president.

Mitch McConnell: (07:07)

Now predictably and foreseeably under the circumstances, members of the mob seemed to interpret this as a further inspiration to lawlessness and violence not surprisingly. Later, even when the president did halfheartedly began calling for peace he didn't call right away for the riot to end. He did not tell the mob to depart until even later. And even then with police officers bleeding and broken glass covering Capitol floors, he kept repeating election laws and praising the criminals. In recent weeks, our ex-president's associates have tried to use the 74 million Americans who voted to reelect him as a kind of human shield against criticism. Using the 74 million who voted for him as kind of a human seal shield against criticism. Anyone who decries his awful behavior is accused of insulting millions of voters. That's an absurd deflection. 74 million Americans did not invade the Capitol, hundreds of rioters did. 74 million Americans did not engineer the campaign of disinformation and rage that provoked it. One person did, just one.

Mitch McConnell: (09:13)

I've made my view of this episode very plain, but our system of government gave the Senate a specific task. The Constitution gives us a particular role. This body is not invited to act as the nation's overarching moral tribunal. We're not free to work backward from whether the accused party might personally deserve some kind of punishment. Justice Joseph Story, our nations first great constitutional scholar, as he explained nearly 200 years ago, the process of impeachment and conviction is a narrow tool. A narrow tool for a narrow purpose. Story explained this limited tool exists to quote, "Secure the state against gross official misdemeanors", end quote. That is to protect the country from government officers. If President Trump were still in office, I would have carefully considered whether the House managers proved their specific charge. By the strict criminal standard the president's speech probably was not incitement.

Mitch McConnell: (10:58)

However, in the context of impeachment, the Senate might have decided this was acceptable shorthand for the reckless actions that preceded the riot. But in this case, the question is moot because former President Trump is constitutionally not eligible for conviction. Now

this is a close question. No doubt. Donald Trump was the president when the House voted. Though, not when the House chose to deliver the paper. Brilliant scholars argue both sides of this jurisdictional question. The text is legitimately ambiguous. I respect my colleagues who've reached either conclusion. But after intense reflection, I believe the best constitutional reading shows that article two, section four, exhausts the set of persons who can legitimately be impeached, tried, or convicted. It's the president, it's the vice-president and civil officers. We have no power to convict and disqualify a former office holder who is now a private citizen.

Mitch McConnell: (12:42)

Here is article two, section four, quote, "The president, the vice-president and all civil officers of the United States shall be removed from office on impeachment for and conviction of treason, bribery, or other high crimes and misdemeanors," end quote. Now, everyone basically agrees that the second half of that sentence exhausts the legitimate grounds for conviction. The debates around the Constitution's framing make that abundantly clear. Congress cannot convict for reasons besides those. It therefore follows that the list of persons in that same sentence is also exhausted. There's no reason why one list would be exhaustive, but the other would not. Article two, section four must limit both why impeachment and conviction can occur and to whom if this revision does not limit impeachment and conviction powers then it has no limits at all. The House has sole power of impeachment and the Senate's sole power to try all impeachments, would create an unlimited circular logic empowering Congress to ban any private citizen from federal office.

Mitch McConnell: (14:25)

Now, that's an incredible claim, but it's the argument of the House managers seem to be making. One manager said the House and Senate have quote, "Absolute unqualified, jurisdictional power", end quote. Well, that was very honest because there is no limiting principle in the constitutional text that would empower the Senate to convict former officers that would not also let them convict and disqualify any private citizen, an absurd end result to which no one subscribes. Article two section four must have force. It tells us the president, the vice president, and civil officers may be impeached and convicted. Donald Trump's no longer the president. Likewise, the provision states that officers subject to impeachment and conviction shall be removed from office if convicted. Shall be removed from office, if convicted. As Justice Story explained, the Senate upon conviction is bound, in all cases, to enter a judgment of removal from office. Removal is mandatory upon conviction.

Mitch McConnell: (16:01)

Clearly he explained that mandatory sentence cannot be applied to someone who's left office. The entire process revolves around removal. If removal becomes impossible, conviction becomes insensible. In one light it certainly does seem counterintuitive that an office holder can elude Senate conviction by resignation or exploration of term, an argument we heard made by the managers. But this underscores that impeachment was never meant to be the final forum for American justice. Never meant to be the final forum for American justice. Impeachment conviction and removal are a specific intra-governmental safety valve. It is not the criminal justice system where individual accountability is the paramount goal. Indeed Justice Story specifically reminded that while former officials were not eligible for impeachment or conviction, they were, and this was extremely important, still liable to be tried and punished in the ordinary tribunals of justice. Put another way in the language of today, President Trump is still liable for everything he did while he was in office as an ordinary citizen. Unless the statute of limitations is run, still liable for everything he did while he was in office.

Mitch McConnell: (18:04)

Didn't get away with anything, yet. Yet. We have a criminal justice system in this country. We have civil litigation and former presidents are not immune from being accountable by either one. I believe the Senate was right not to grab power the Constitution doesn't give us. And the Senate was right not to entertain some light speed sham process to try to outrun the loss of jurisdiction. It took both sides more than a week just to produce their pre-trial briefs. Speaker Pelosi's own scheduling decisions conceded what President Biden publicly confirmed, a Senate verdict before inauguration day was never possible. Now, Mr. President this has been a dispiriting time, but the Senate had done our duty. The framers' firewall helped held up again. Oh, in January the sixth, we returned to our posts and certified the election. We were uncowed. We were not intimidated. We finished the job. And since then we resisted the climber to defy our own constitutional guardrails in hot pursuit of a particular outcome.

Mitch McConnell: (19:48)

We refused to continue a cycle of recklessness by straining our own constitutional boundaries in response. The Senate's decision today does not condone anything that happened on or before that terrible day. It simply shows that senators did what the former president failed to do. We put our constitutional duty first.

- 763)** 2021-02-16 Wosinska M, Zavodszky A, Romine M, McClellan M: Promising practices for promoting utilization of COVID-19 monoclonal antibody treatments. Duke Margolis Center for Health Policy, February 16, 2021.

<https://healthpolicy.duke.edu/sites/default/files/2021-02/Promising%20Practices%20for%20Promoting%20Utilization%20of%20COVID-19%20Monoclonal%20Antibody%20Treatmentsv4.pdf>

- 764)** 2021-02-16. Malani PN, Golub RM: Neutralizing monoclonal antibody for mild to moderate COVID-19. JAMA February 16, 2021; 325(7): 644-645.

<https://jamanetwork.com/journals/jama/fullarticle/2775645>

- 765)** 2021-02-16 Gottlieb RL, Nirula A, Chen P, Boscia J, Heller B, Morris J, Huhn G, Cardona J, Mocheria B, Stosor V, Shawa I, Kumar P, Adams AC, van Naarden J, Custer KL, Durante M, Oakley G, Schade AE, Holzer TR, Ebert PJ, Higgs RE, Kallewaard NL, Sabo J, Patel DR, Klekotka P, Shen L, Skovronsky DM: Effect of Bamlanivimab as monotherapy or in combination with Estevimab on viral load in patients with mild to moderate COVID-19: A randomized clinical trial. JAMA 2021 Feb 16; 325 (7): 632-644.

[file:///Users/andrusmd/Downloads/jama\\_gottlieb\\_2021\\_oj\\_210002\\_1613412631.85755%20\(2\).pdf](file:///Users/andrusmd/Downloads/jama_gottlieb_2021_oj_210002_1613412631.85755%20(2).pdf)

**MAIN OUTCOMES AND MEASURES** The primary end point was change in SARS-CoV-2 log viral load at day 11 ( $\pm 4$  days). Nine prespecified secondary outcome measures were evaluated with comparisons between each treatment group and placebo, and included 3 other measures of viral load, 5 on symptoms, and 1 measure of clinical outcome (the proportion of patients with a COVID-19-related hospitalization, an emergency department [ED] visit, or death at day 29).

**RESULTS** Among the 577 patients who were randomized and received an infusion (mean age, 44.7 [SD, 15.7] years; 315 [54.6%] women), 533 (92.4%) completed the efficacy evaluation period (day 29). The change in log viral load from baseline at day 11 was  $-3.72$  for 700 mg,  $-4.08$

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for 2800 mg, -3.49 for 7000 mg, -4.37 for combination treatment, and -3.80 for placebo. Compared with placebo, the differences in the change in log viral load at day 11 were 0.09 (95% CI, -0.35 to 0.52; P = .69) for 700 mg, -0.27 (95% CI, -0.71 to 0.16; P = .21) for 2800 mg, 0.31 (95% CI, -0.13 to 0.76; P = .16) for 7000 mg, and -0.57 (95% CI, -1.00 to -0.14; P = .01) for combination treatment. Among the secondary outcome measures, differences between each treatment group vs the placebo group were statistically significant for 10 of 84 endpoints. The proportion of patients with COVID-19-related hospitalizations or ED visits was 5.8% (9 events) for placebo, 1.0% (1 event) for 700 mg, 1.9% (2 events) for 2800 mg, 2.0% (2 events) for 7000 mg, and 0.9% (1 event) for combination treatment. Immediate hypersensitivity reactions were reported in 9 patients (6 bamlanivimab, 2 combination treatment, and 1 placebo). No deaths occurred during the study treatment.

**CONCLUSIONS AND RELEVANCE** Among nonhospitalized patients with mild to moderate COVID-19 illness, treatment with bamlanivimab and etesevimab, compared with placebo, was associated with a statistically significant reduction in SARS-CoV-2 viral load at day 11; no significant difference in viral load reduction was observed for bamlanivimab monotherapy. Further ongoing clinical trials will focus on assessing the clinical benefit of anti-spike neutralizing antibodies in patients with COVID-19 as a primary end point.

**TRIAL REGISTRATION** ClinicalTrials.gov Identifier: NCT04427501

- 766) 2021-02-16 U.S. Food & Drug Administration: Clinical Memorandum. COVID-19 Convalescent Plasma EUA Decision Memo. <https://www.fda.gov/media/141480/download> is the baseline URL which when placed in the Wayback Machine, 8-23-2020 to 2-2021 is the renewed new memo on CCP EUA issued 2-2021 to the present: <https://web.archive.org/web/20210330024720/https://www.fda.gov/media/141480/download>

## EXECUTIVE SUMMARY

COVID-19 Convalescent Plasma (CCP) was granted Emergency Use Authorization (EUA) for the treatment of hospitalized patients with COVID-19 on August 23, 2020. At that time, the totality of the scientific evidence supported a determination that the use of CCP in hospitalized patients with COVID-19 met the “may be effective” standard for issuance of an EUA, and it was reasonable to consider that the known and potential benefits of CCP outweighed the known and potential risks for the authorized use.

Following the EUA, emerging evidence from randomized controlled trials has continued to inform this assessment. The available evidence indicates that 1) the use of low titer CCP in hospitalized patients no longer meets the evidentiary standard of “may be effective”, and 2) **high titer CCP has not demonstrated benefit when administered late in the disease course in immunocompetent hospitalized patients.**

Additional data from RCTs and observational studies support a determination that **high titer CCP may be effective when administered early in the course of illness, particularly prior to the expected time of host antibody response.** In patients with impaired humoral immunity, the potential therapeutic window may be prolonged. As RCT data continue to demonstrate that the risks of CCP do not exceed those observed with plasma transfusion in general, it is reasonable to believe that the known and potential benefits of use of high titer CCP outweigh the known and potential risks when used for the treatment of hospitalized patients with COVID-19, **particularly early in the course of illness or in patients with impaired humoral immunity.** Results from ongoing RCTs are expected to continue inform the optimal patient populations and product characteristics for efficacy of CCP in COVID-19.

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**Recommendation:** The conditions of Emergency Use Authorization for CCP for the treatment of hospitalized patients with COVID-19 should be revised to exclude the use of low titer CCP. High titer CCP continues to meet criteria for Emergency Use Authorization for the treatment of hospitalized patients with COVID-19 early in the course of hospitalization. The letter of authorization and accompanying fact sheets should be revised to emphasize early administration of CCP in the absence of immunodeficiency or immunosuppression. Additional results from adequate and well-controlled trials will continue to be evaluated to further characterize the patient populations and product characteristics meeting EUA criteria  
.....

*Antibody responses in COVID-19 and timing of CCP transfusion*

The relative roles of humoral and cellular immunity in SARS-CoV-2 infection continue to be unraveled, and it appears likely that CD4+ T cells, CD8+ T cells, and neutralizing antibody responses all contribute to control of SARS-CoV-2 infection in both non-hospitalized and hospitalized cases of COVID-19[23]. The large majority of patients with SARS-CoV-2 infection will seroconvert within 5-15 days post-symptom onset, with 90% seroconverting by day 10[23-25]. IgM and IgG antibodies are frequently detected concurrently[26], and peak anti-spike or anti-RBD IgG levels are reached by approximately 15 days post symptom onset[27]. Antibody responses and memory B cells appear to persist for at least 5 months and antibodies may be a correlate of immune protection[28-31]. Delayed antibody response kinetics also appear to be associated with more severe disease[27, 32]. At the same time, studies have generally shown higher titers in patients following recovery from severe disease compared to mild or asymptomatic illness[25, 33].

The observation that high titer CCP was beneficial when administered within 72 hours of symptom onset in high risk subjects, but failed to demonstrate benefit in trials where the median duration of symptoms was 8 days or longer, indicates benefit with CCP transfusion is more likely in patients early in the humoral immune response when host antibody titers remain undetectable or low (i.e., likely within the first week following symptom onset). This is consistent with longstanding historical precedent in passive immune therapies for viral infections, where prophylactic or early use has generally been more effective than in established infections[34].

These trends are also consistent with clinical evidence for administration of anti-SARS-CoV-2 monoclonal antibodies, where benefit has been demonstrated with early outpatient use, but not in hospitalized patients within 12 days of symptom onset[35-37] as described in the following two studies:

In outpatient studies of bamlanivimab in recently diagnosed patients with mild to moderate disease (BLAZE-1)[36], subjects were excluded if they were previously known to be seropositive. Subjects had a median of 4 days of symptoms at the time of infusion, and the study found one of three doses of neutralizing antibody LY-CoV555 appeared to accelerate the natural decline in viral load over time. While reduction in viral load was the primary endpoint in this phase 2 trial, subjects treated with bamlanivimab also showed a nominally statistically significant reduction in COVID-19 related hospitalizations or ED visits within 28 days in the pooled dose-level data.

In outpatient studies of casirivimab/imdevimab in symptomatic patients with mild to moderate COVID-19 (R10933-10987-COV-2067), subjects who were no more than 7 days from symptom enrollment were included regardless of serostatus[35]. Casirivimab/imdevimab treatment reduced viral load, and patients who were seronegative at baseline showed larger reductions in



viral load and a larger reduction in the proportion of subjects with at least one medically attended visit compared to the overall population. Based on these studies, both therapies were granted EUA for use in high risk outpatients with mild to moderate COVID-19 (<https://www.fda.gov/media/143892/download>, <https://www.fda.gov/media/143603/download> ).

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In early studies of the COVID-19 pandemic, the median time from symptom onset to the development of dyspnea was approximately 5-8 days[38, 39], and patients who develop critical illness typically do so shortly thereafter (days 8-10)[40]. While the study by Libster et al[10] demonstrated a reduction in progression to severe disease in high risk outpatients within 72 hours of the onset of symptoms, one factor complicating very early use of CCP in the outpatient population is the evidence that a large proportion of these patients will have a self-limited illness and will not go on to severe or critical illness even without targeted intervention[41]. Therefore, in the early-disease outpatient population, it is important to have a full understanding of the relative benefit and identify high-risk populations so that the known and potential risks of transfusion are outweighed by the known and potential benefits of CCP. Ongoing randomized controlled trials will be critical to determine the clinical and laboratory parameters that can identify where the potential benefit of CCP outweighs the potential risk in outpatients.

Based on the study by Libster et al[10] the therapeutic window appears to be at least within 72 hours of symptom onset, while additional negative RCTs with a median duration of symptoms prior to transfusion of 8 days indicating that 8 days after symptom onset may be too late for efficacy of CCP in immunocompetent hospitalized COVID-19 patients. These timepoints appear to correlate with the timing of the patients' own antibody responses to infection, such that by the time a patient is forming their own antibodies, benefit from CCP appears unlikely. The time period between 3 and 7 days remains to be studied rigorously in randomized trials of CCP, but observational studies, preclinical studies, studies of related therapies, and what is known about the timing of the adaptive immune response in SARS-CoV-2 infection suggest that high titer CCP may be effective in this window period. As noted above, this window appears to be longer in the setting of impaired or deficient humoral immunity. Nonetheless, adequate and well controlled trials in this time period remain necessary for a conclusive demonstration of efficacy.

- 767) 2021-02-16 Centers for Disease Control and Prevention: Interim clinical guidance for management of patients with confirmed coronavirus disease (COVID-19). Most recent update.

<http://web.archive.org/web/20210408021730/https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-guidance-management-patients.html>

- 768) 2021-02-17 Wilt TJ, Kaka AS, MacDonald R, Linskens E, Obley A, Vela K, Duan-Porter W: COVID-19: Remdesivir for Adults – A Living Review. Updated February 2021, Health Services Research & Development Service, U.S. Department of Veterans Affairs.

<https://web.archive.org/web/20210319093451/https://www.hsrd.research.va.gov/publications/esp/covid-19-remdesivir.cfm>

- 769) 2021-02-17 Sauber R: Letter to Michael R. Hogan, Designated Agency Ethics Official...In a letter of February 17, 2021.

[https://extapps2.oge.gov/201/Presiden.nsf/PAS+Index/249BEDEAC38845E48525868D0032DC51/\\$FILE/Sauber,%20Richard%20%20finalEA.pdf](https://extapps2.oge.gov/201/Presiden.nsf/PAS+Index/249BEDEAC38845E48525868D0032DC51/$FILE/Sauber,%20Richard%20%20finalEA.pdf)

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- 770) 2021-02-18 **Katz LM: (A Little) Clarity on convalescent plasma for Covid-19.** Initially published on January 13, 2021) This editorial was republished in the N Engl J Med, 2021 Feb 18; 384 (7): 666 – 668. <https://www.nejm.org/doi/full/10.1056/NEJMe2035678> In the article, it was not disclosed that Dr. Katz is the Chief Medical Director, ImpactLife: <https://www.bloodcenter.org/about/news/authors/dr-louis-katz-a4/>

[Please note that Dr. Katz was not fully identified by this paper. Dr. Katz is "...the former Chief Medical Officer at America's Blood Centers in Washington, DC, an ABC past president, former board member and a past chair of its Scientific, Medical and Technical Committee. His transfusion medicine career has been dominated by attention to transfusion transmitted infections. He has served multiple terms as the chair of the AABB Transfusion Transmitted Diseases committee and served on many AABB committee and working groups. Dr. Katz is on the Editorial Board of the journal Transfusion, has served on the FDA Blood Products Advisory Committee as a member, industry representative and chair, and is a current member of the HHS Advisory Committee on Blood and Tissue Safety and Availability." – Winn KI, Katz L, Goel R: Dr. Louis Katz, Acting Chief Medical Director. ImpactLife (formerly Mississippi Valley Regional Blood Center). <https://www.bloodcenter.org/about/news/authors/dr-louis-katz-a4/> ]

*The text of this article that follows is verbatim because it explains the mindset of those involved in the FDA's, NIH's, and The White House's convoluted obfuscation in the lack of treatment during the viremic phase of those infected with COVID-19 with passive immunization (Covid-19 Convalescent Plasma [CCP]) AND THE COVER-UP by US Medicine and the US Government THAT HAS BEEN PERVASIVE OVER THE LAST 15 months. While advocating for the appropriate administration early in the viremic phase of Covid-19 (<72 hours from symptoms/diagnosis) in the outpatient setting and NOT IN THE HOSPITAL SETTING, this New England Journal of Medicine editorial fails strongly to emphasis the definitive utility of PASSIVE IMMUNIZATION and thus has been ignored by the medical community, the US federal government, and the US public-at-large. Even after the FDA quietly removed from all its official documentation on 9/2/2020 mandating the strict erroneous CCP administration criteria initiated by the FDA / vis-à-vis The White House on March 24, 2020 for use only in severely affected patients--late in the disease--administration of CCP (during the cytokine cascade and bradykinin phase which both are dominant in severely hospitalized patients and then only somewhat effective treatment is supportive) continued. The wrong-time administration of CCP became the de facto standard-of-care. The majority of 722,000 doses of CCP given over the last 15 months to individuals late in their disease course throughout the U.S.A. (and much of the World) was given at the WRONG TIME. –*

And the FDA, the NIH, the VA, The White House,  
the New England Journal of Medicine, etc.  
*knew it!*

PASSIVE IMMUNOTHERAPY has been used since the late 19th century, and in 1901, the first Nobel Prize in Physiology or Medicine was awarded for serum therapy for patients with diphtheria. During the 1918 pandemic, serum from convalescent patients was used to treat influenza, with some apparent success.<sup>1</sup> Today, the use of immunoglobulins has been established for the prophylaxis and treatment of a variety of infections, including those with respiratory syncytial virus, cytomegalovirus, and hepatitis B or hepatitis A virus. More recently, passive immunotherapy has been evaluated for severe acute respiratory syndrome (SARS), Middle East respiratory syndrome, and Ebola virus disease. Intravenous human immunoglobulin has revolutionized the management of immunoglobulin deficiency states.

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The use of convalescent plasma against SARS coronavirus 2 (SARS-CoV-2) is advocated for the treatment of patients with coronavirus disease 2019 (Covid-19). The experience with influenza A is relevant, and a meta-analysis suggested that **early treatment, before critical illness develops**, may be an important **predictor of the efficacy of passive immunotherapy for that pathogen.**<sup>1</sup> The authors of that meta-analysis acknowledged the low quality of the available evidence regarding early treatment. Another meta-analysis of studies of convalescent plasma and hyperimmune immunoglobulin in patients with influenza A and SARS suggested a mortality benefit **“when convalescent plasma is administered early after symptom onset.”**<sup>2</sup> However, in a randomized, controlled trial, high-titer convalescent plasma from patients who had recovered from H1N1 influenza was ineffective against severe influenza A infection in hospitalized children and adults.<sup>3</sup>

**Initial randomized trials of convalescent plasma in patients with Covid-19 focused on hospitalized patients who were already moderately to severely ill**, and these trials provided weak evidence of clinical efficacy.<sup>4-6</sup> **Some were underpowered** when nonpharmaceutical interventions such as masking and social and physical distancing reduced the incidence of Covid-19 and enrollment was limited. Also, these trials were heterogeneous with respect to the characteristics of the convalescent plasma used (e.g., its antibody content and the stratification of the recipients according to their serologic status). **No unexpected safety signals beyond the recognized risks of plasma transfusion (i.e., fluid overload, transfusion-associated acute lung injury, and allergy) have emerged, nor has there been evidence of antibody-dependent enhancement of Covid-19 severity.** Accordingly, it is difficult to make actionable conclusions about the clinical value of convalescent plasma.

Observational studies have been more positive than randomized trials; some, but not all, of these studies have suggested modest clinical effects and measurable surrogate virologic outcomes.<sup>7,8</sup> They have confirmed the safety profile of plasma transfusions but have some of the same issues as randomized trials, in addition to the potential biases and shortcomings inherent in observational studies.

The Food and Drug Administration (FDA) argued that a “totality of the evidence” suggested that the benefits of convalescent plasma would outweigh its risks, and given the lack of effective treatments, **the FDA granted an Emergency Use Authorization (EUA) and provided guidance on the manufacture and use of convalescent plasma in hospitalized patients with signs of progressive infection.** By contrast, a National Institutes of Health guidelines panel stated that “the data are insufficient to recommend for or against” the use of convalescent plasma. The Infectious Diseases Society of America and the AABB (formerly known as the American Association of Blood Banks) recommend that the use of convalescent plasma be limited to clinical trials, that critically ill patients and **those in the intensive care unit (ICU) are unlikely to benefit from transfusions of convalescent plasma**, and that **convalescent plasma should be used as early as possible in the course of infection (preferably within 3 days after diagnosis) in order to achieve the best outcomes.**<sup>9</sup>

Considering the number of SARS-CoV-2 infections, the paucity of treatment options, and the enthusiasm for and controversy about convalescent plasma, a high-quality, multicenter, randomized, controlled trial is most welcome. **Libster and colleagues now report in the *Journal*<sup>10</sup> the results of a well-executed trial of early convalescent plasma in older adult patients in whom symptomatic SARS-CoV-2 infection was diagnosed with the use of a polymerase-chain-reaction assay. In this double-blind trial, 250 ml of convalescent plasma with an IgG titer greater than 1:1000 against SARS-CoV-2 spike (S) protein was compared with saline placebo in patients who were 65 to 74 years of age and had prespecified**

**coexisting conditions and in patients who were 75 years of age or older with or without coexisting conditions.**

The patients received convalescent plasma or placebo less than 72 hours after symptom onset. In the intention-to-treat population, a primary end-point event (progression to predefined severe disease during follow-up) occurred in 16% (13 of 80 patients) and 31% (25 of 80 patients) of the well-matched convalescent plasma and placebo groups, respectively. A dose-dependent effect relative to the antibody titers after infusion was observed, and this effect was larger after the exclusion of 6 patients who had a primary end-point event before infusion. The benefits of convalescent plasma with respect to the secondary end points were consistent with those associated with the primary end point. No serious adverse events were observed. **The authors conclude that “early administration of high-titer convalescent plasma against SARS-CoV-2 to mildly ill infected older adults reduced the progression of Covid-19.”** Even before the current trial, **the EUA emphasized the potential advantages of early therapy with high-titer convalescent plasma.** Unfortunately, a direct comparison of antibody levels in the current trial with assays specified in the FDA EUA is not available. Antibody titers in the recipients at enrollment were not provided, so no comment can be made about the usefulness of seroreactivity in patients as a criterion for convalescent plasma use.

At this time, convalescent plasma should be reserved for patients in whom the duration, severity, and risk of progression of illness are similar to those in the patients in this trial. Younger high-risk patients (and certain immunodeficient patients) with these disease characteristics should be considered as well.

The supply of convalescent plasma has been tenuous during the marked increase in Covid-19 cases during the fall in the United States, although recent collections have improved. From September 28 through December 27, 2020, distributions of new and stockpiled units of convalescent plasma to hospitals in the United States exceeded collections by 7785 units (Block W: personal communication). **If collections are restricted to the high-antibody titers and patient indications described in the article by Libster et al., the supply of convalescent plasma will be stressed. At my center, high-titer collections (as defined by the FDA) account for only 19.5% of seroreactive convalescent plasma donations. Shifting the pool of potential recipients away from those included in the EUA to the many infected outpatients whose risk of hospitalization and eventual need for advanced care cannot be precisely estimated should lead to the extension of convalescent plasma transfusions to prehospital venues (although this is not yet permitted in the EUA).**

**Uncontrolled compassionate use of convalescent plasma in patients other than those with an early infection that is likely to progress to more severe illness should be discouraged,** even though clinicians recognize how difficult it can be to “just stand there” at the bedside of a patient in the ICU. Constraints on therapies for Covid-19 that are effective for limited patient populations are a powerful argument for continued consistent adherence to recommended nonpharmaceutical interventions and the rapid deployment and uptake of effective vaccines.

In an obfuscating way, Dr. Katz confirms that when high-dose COVID-19 Convalescent Plasma is given **EARLY**(<72 from time of onset or diagnosis) and is compared with placebo in age-matched patients ~70 years of age, progression to severe COVID-19 disease (e.g. pneumonitis, blood clots, etc.) is 16% versus 31%, respectively.

**THUS, COVID-19 CONVALESCENT PLASMA when given EARLY to an AGE COHESIVE GROUP in the VIREMIC PHASE OF COVID-19 (<72 HOURS) has a 50% DECREASED / OBSERVED REDUCTION IN PROGRESSION to the LATER MULTIORGAN-SYSTEM PHASE**

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**Treatment:** Passive Immunization: COVID-19 Convalescent Plasma and Antibodies and Antivirals  
**Prevention:** Active Immunization: Vaccines

## **OF COVID-19 INVOLVING (1) THE CYTOKINE CASCADE STORM and (2) the ACCUMULATION OF DETRIMENTAL LEVELS OF BRADYKININ.**

- 771) 2021-02-18 Whyte J: FDA revises EUA for COVID-19 Convalescent Plasma. WebMD. John Whyte, M.D., Chief Medical Officer at WebMD interviews Peter Marks, M.D., PhD, Director for the Center for Biologics Evaluation and Research at the U.S. FDA: FDA revises EUA for COVID-19 convalescent plasma. <https://www.webmd.com/coronavirus-in-context/video/peter-marks-plasma>

*The following is a very important interview as Peter Marks, M.D., PhD as the Director for CBER at the FDA had the ability in March 2020 to have designated COVID-19 Convalescent Plasma a Biosimilar Biologic (like rabies vaccine, HyperTet, RhoGam, IVIG, etc.) and the designation of "Investigational" and all the Expanded Access / (compassionate use only) would have been avoided. This would have precluded the issuing of the eligibility criteria of March 24, 2020 which directed administration late in the course of the disease—THE WRONG TIME as is confirmed by Dr. Marks in the 2/18/2021 interview! Immediately following is from the March 24, 2021 FDA announcement. [https://notifylibrary.org/sites/default/files/Investigational%20COVID-19%20Convalescent%20Plasma%20-%20Emergency%20INDs%20\\_%20FDA.pdf](https://notifylibrary.org/sites/default/files/Investigational%20COVID-19%20Convalescent%20Plasma%20-%20Emergency%20INDs%20_%20FDA.pdf)*

The container label of COVID-19 convalescent plasma units must include the following statement, "Caution: New Drug--Limited by Federal (or United States) law to investigational use." (21 CFR 312.6 (a))



- **Eligible patients for use under expanded access provisions:**

- Must have laboratory confirmed COVID-19
- Must have severe or immediately life-threatening COVID-19, for example:<sup>1</sup>
  - Severe disease is defined as:
    - dyspnea,
    - respiratory frequency  $\geq 30/\text{min}$ ,
    - blood oxygen saturation  $\leq 93\%$ ,
    - partial pressure of arterial oxygen to fraction of inspired oxygen ratio  $< 300$ , and/or
    - lung infiltrates  $> 50\%$  within 24 to 48 hours
  - Life-threatening disease is defined as:
    - respiratory failure,
    - septic shock, and/or

<https://www.fda.gov/vaccines-blood-biologics/investigational-new-drug-ind-or-device-exemption-ide-process-cber/investigational-covid-19-convale...> 2/3

27/3/2020

Investigational COVID-19 Convalescent Plasma - Emergency INDs | FDA

- multiple organ dysfunction or failure
- Must provide informed consent

*In addition to the above, FDA is continuing to work with its government partners including the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC) to develop master protocols for use by multiple investigators in order to coordinate the collection and use of COVID-19 convalescent plasma.*

<sup>1</sup>Wu Z, McGoogan JM. Characteristics of and Important Lessons From the Coronavirus Disease 2019 (COVID-19) Outbreak in China: Summary of a Report of 72 314 Cases From the Chinese Center for Disease Control and Prevention. *JAMA*. Published online February 24, 2020. doi:10.1001/jama.2020.2648

## Start of the interview of Dr. Marks by Dr. Whyte:

JOHN WHYTE: Welcome, everyone. You're watching "Coronavirus in Context." I'm Dr. John Whyte, chief medical officer at WebMD. We're spending a lot of time talking about vaccines. But we can't forget about the role of therapeutics for those persons who have caught COVID and are having a serious case. And there's been some recent changes in when and how we should use convalescent plasma.

So to help explain these changes, I've asked Dr. Peter Marks. He's the director for the Center for Biologics Evaluation and Research at the US Food and Drug Administration. Welcome back, Dr. Marks.

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**Treatment:** Passive Immunization: COVID-19 Convalescent Plasma and Antibodies and Antivirals  
**Prevention:** Active Immunization: Vaccines

PETER MARKS: Thanks very much for having me.

JOHN WHYTE: Let's just take a minute and remind our audience-- we have a lot of folks from Medscape, but also consumers-- what is convalescent plasma?

**PETER MARKS:** So convalescent plasma is the blood plasma that's taken from an individual who has been infected with COVID-19 and who's recovered from the infection. In some cases, they might not even have known they had the infection, but they obviously did. And they might have antibodies that have been detected and told they had COVID-19, or they might have had a PCR test when they were sick with COVID, were told they had COVID-19, and afterwards, after they recover and they're fully recovered, they're eligible to potentially donate convalescent plasma, which is usually taken by plasmapheresis. People are put on a machine for about an hour, and the blood products taken out. And the blood cells are given back to the person. The plasma is taken off.

JOHN WHYTE: Now, the FDA authorized the use, under an emergency use authorization, of convalescent plasma in August of last year. And recently, you revised that authorization-- actually, in many ways made it more restrictive. Let's go over what the change in the EUA is.

PETER MARKS: Right. So the emergency use authorization that was issued in August was a very broad emergency use authorization, because at that time we were relying on the evidence at the time which said that it appeared that convalescent plasma could potentially benefit a broad swath of people. And we weren't really sure who it might benefit the absolute most. We knew it was best when given in high titer, and we knew that it seemed to be best in people who were treated earlier. But we couldn't rule out that it was having some benefit to people later on in the course of disease.

JOHN WHYTE: And at that time, they didn't have to be hospitalized.

**PETER MARKS:** We always required that the patients be hospitalized. It was always hospitalized patients. And what happened, then, is over the course of the past few months-- we follow the literature very closely-- there have been studies that have come out of various places. Some have been negative for convalescent plasma-- they said that it's not had a beneficial effect. Others have been quite positive.

And over the course of time, we've looked closely at them, and we sorted them out. And it became pretty clear that when people were treated early on with high-titer convalescent plasma, they seemed to be showing some benefit. And when you treat late, you just don't see that benefit. Particularly when you treat people who have been on a ventilator, it just-- with the rare exception of people who have defects in immunity, people who have diseases like hematologic malignancies like chronic lymphocytic leukemia-- those people, they may benefit late on, because they don't make antibodies.

But for the large majority of people who have normal immune systems, if you treat late, convalescent plasma is not seeming to benefit, whereas if you treat early, within the first few days after diagnosis, the data are increasingly supporting that there is some benefit there. It's not a massive benefit. It's a modest benefit.

JOHN WHYTE: How would you articulate that benefit?

**PETER MARKS:** I can cite the data that we have from roughly 20,000 individuals who received 1 unit of convalescent plasma. Roughly half of those people got high titer and half of them got low titer of various levels. And the people who got the higher-titer plasma had about a 2-percent absolute reduction in mortality at seven days, which translates into about a 15-percent relative reduction if they were not intubated.

If they were intubated, they were on a ventilator, then there really wasn't any benefit. So those data really helped push us along towards saying it was time to kind of narrow down the emergency use authorization to say, look, don't use this late in people who are intubated-- that is, on a ventilator. Use it early on or earlier on in the course of disease.

Now, your next question might be, why not just use it as an outpatient? Hum. And the answer is--

JOHN WHYTE: Now you're interviewing yourself.

PETER MARKS: Nah. I might as well do that. I've done this enough. But the reason why we're not there yet is because we're waiting for some very well-designed studies that are being conducted, one by the National Heart, Lung, and Blood Institute, which will give us a good answer about the potential benefit in that setting.

JOHN WHYTE: Well, that's why I was asking you about hospitalized patients. Because if we talk about-- you mentioned it has to be used early on in the disease-- but what about severity of disease? Because many patients that aren't coming to the hospital until they're much further along-- so how do you do it, in the sense you want to do it early on, within those first couple of days, but sometimes we're telling patients not to come to the hospital or to the ER. So how do we balance that? So what's the severity of disease?

PETER MARKS: I think right now the way we balance it is we say that if you're somebody who's got early disease and you're interested, get onto the [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov) and find one of the sites around you that might be doing outpatient clinical trials with convalescent plasma. There are a number of sites doing that.

But I think, otherwise, when people are admitted to the hospital, it's probably a good thing for physicians to think right away, is this somebody for whom convalescent plasma may make sense? Again, if someone's intubated in that first couple of days, maybe not. On the other hand, if someone needs supplemental oxygen, those patients did seem to benefit.

JOHN WHYTE: Now, let's talk about the person's underlying immune response, their humoral immunity. So who are those patients? Many patients are often asking about, what if they're immunocompromised? What do they qualify for? Talk to our listeners about what's that patient population-- because that's a component, their underlying immunity function.

PETER MARKS: So it's a great question. And we've actually kept up with the case reports that have been coming out. They're not trials, but they're a case series that have come out from around the globe, and it's very convergent. If you treat people who don't make a sufficient amount of antibody, either because they have a primary immunodeficiency syndrome or because they have [INAUDIBLE] cancer, and they can't make them, if you treat them, even if you seem to treat those people late, they seem to have benefit.

And there are some amazing case reports-- obviously, it's always N-of-1-- case reports, you always have to take with a grain of salt-- but where people even very late on have had very good responses clearing viremia. So that kind of makes sense, right? Because if you're not able-- what we think, at least, that the antibodies are doing here-- the antibodies in convalescent plasma are acting like an antiviral, right? And if you give it early, they're acting like an antiviral would early on in getting things under control. Later on in the course of disease, where there are other organ damage effects, that's not the best time for an antiviral. And for those who are immunocompromised, it may be that they just have ongoing viremia, and you need to clear it. And giving them convalescent plasma helps take care of that.

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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*  
**Prevention:** *Active Immunization:* Vaccines

JOHN WHYTE: One question we have gotten asked, Dr. Marks, is for those patients who have been fully immunized, are they able to donate plasma?

PETER MARKS: So it's a great question. And it's one we're still debating. Right now, if people have not had COVID-19 and get immunized-- so they're people who are COVID-19-negative to start, then get immunized-- we're not considering them as convalescent plasma donors, because they're making antibodies against just the S protein that are in the current generation of mRNA vaccines that are authorized.

We don't know, in terms of the convalescent plasma response that we're seeing, how much of the benefit is from the S-protein antibodies versus N-protein antibodies or other antibodies that are there. And until we have a little better idea on that, we're a little hesitant to swing over to have vaccinated individuals donate.

But this is an absolutely great question, because we're very much looking into this now. It would be nice to understand, because soon we're going to have a large population of people who will be fully vaccinated, probably with high titers of S antibodies, and it would be nice to know this. So stay tuned. We do that for other infectious diseases, and maybe we'll see it coming for COVID-19 soon enough.

JOHN WHYTE: Tell us how staff are doing. You had your general work that you had to do, in terms of vaccines, other biologics. Now you have the whole issue of COVID. How is everyone managing it?

PETER MARKS: Well, I have to say, we are incredibly lucky at FDA. We have a staff that has risen to the occasion in an amazing way. They're keeping the normal freight moving. And while they're keeping the normal freight moving, they are taking care of the avalanche of COVID-19-related applications.

Now, in some areas, there are a little lower number of applications than in others. But if you look, for instance, in the vaccine area, there is an avalanche there. And they're doing an incredible job keeping up. Same thing with, actually, some of the cellular therapies that have come in, and even the antibody therapies, et cetera. There are lots of them, right?

Our folks have done just an incredible job pitching in. People who have a little less work pitch in to those who are almost getting underwater in work. So it's been really wonderful. It has taken its toll. People are getting a little tired. And we're trying to make sure that we take care of people. But we're very lucky that people have really had such commitment to public health.

JOHN WHYTE: Absolutely. And then finally, all these emergency use authorizations that are happening across the agency-- do you expect sponsors to apply for full licensure in a few months?

PETER MARKS: Yeah. So I-- for the vaccine sponsors in particular, we've told them that if they want to come in for an EUA, they should expect-- it's actually in our guidance-- they should expect that they're going to come in for a biologics license application. And so that's why the work isn't going to end soon, because as we're now dealing with some of the emergency use authorizations where the vaccines are becoming more mature, they've been in use for a little bit, I would suspect in the not-too-distant future we may see their biologics license applications. And so there will be kind of a cohort that will come along of license applications in the coming months.

JOHN WHYTE: Well, Dr. Marks, I want to thank you for taking the time, the work that you and all the staff at the Center for Biologics Evaluation and Research and all of FDA are doing to keep us all safe.

PETER MARKS: Thanks so much for having me today.

JOHN WHYTE: And if you have any questions about COVID, drop me a line. You can email us at [drjohn@webmd.net](mailto:drjohn@webmd.net) as well as post it on Facebook, Twitter, and Instagram. Thanks for watching.

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*When severely ill with COVID-19, a person experiences two phases – an early phase dominated by the virus reproducing itself, which happens a lot in the lungs and leads to low oxygen levels; and a later phase where the body's immune system has a dangerous overreaction to the infection, which causes damage to other organs.*

*“The early phase, when the virus is really doing most of its reproduction and a lot damage, that's when we want to interfere with that reproduction. And that's what these antibodies do,” said Dr. Bruce Hall\*, chief quality officer for BJC HealthCare.*

*That's why it's important to get tested at the first signs of illness and immediately contact a doctor, who must assess and refer patients for the infusion therapy, Hall said.*



*The infusion takes about an hour, and patients are observed for another hour for any adverse reactions, the providers said. The centers are designed so infected patients do not share any space or entrances with other patients, some even requiring their own elevator.*

*Monoclonal antibody therapies for COVID-19 made by Eli Lilly and Regeneron were **approved for emergency use by the FDA** in November. To ensure access, the U.S. Department of Health and Human Services purchased over a million doses of the therapies and made them available to states at no cost. Doses are free of charge to patients.*

*The treatments have faced barriers to getting started, however, because of the time and logistics involved for the infusions.*

*Hospitals were swamped with caring for patients during the hardest-hit months of the pandemic and then tasked with setting up vaccinations. Many patients also may not know about the therapies or have the perceptions that they are only available to the well-connected, as they gained publicity when used by former President Donald Trump and other politicians. [e.g.: Trump, Carson, Christy, Giuliani, etc]*

*"It takes a little bit of effort to arrange and coordinate and manage the patients appropriately, but we think that it's all worth it if we can keep patients out of the hospital," said **Hall** with BJC, which has infusion centers at Christian Hospital in north St. Louis County, a Missouri Baptist Medical Center Clinic in Sunset Hills, Memorial Hospital in Belleville, Barnes-Jewish Hospital in St. Louis, and Boone Hospital Center in Columbia, Missouri.*

*Studies show that for every 15 people treated, one will be saved from needing to be hospitalized with COVID-19, **Hall** said. So far, the BJC locations are seeing similar results.*

*"That's probably a 30 to 40% reduction or more in terms of the risk of having to go into the hospital," he said. "For a disease that can be fatal, we are reducing that need to go into the hospital substantially."*

\* Bruce Hall, M.D., Ph.D., F.A.C.S., Professor of Surgery, Washington University School of Medicine (WUSOM). Through the VA-University Affiliation of 1946\*\*, PL 79-293, both Dr. Hall and I are Attending Surgeons at the St. Louis (John Cochran) VAMC and Professors of Surgery from our respective universities: WUSOM and Saint Louis University School of Medicine (SLUSOM). Our desks are across the hall from each other on 5N of JCVAMC in A558, Unit I [WU] General Surgery and in A555, Unit II [SLU] General Surgery, respectively. Bruce's cell is: 314-401-0247 and my wife, Pam's cell is: 314-809-9634.

\*\* U.S. Department of Veterans Affairs Research and Development: Milestones in VA-Academic Collaboration, [https://www.research.va.gov/researchweek/press\\_packet/Collaboration.pdf](https://www.research.va.gov/researchweek/press_packet/Collaboration.pdf), December 2016.

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**Treatment:** Passive Immunization: COVID-19 Convalescent Plasma and Antibodies and Antivirals  
**Prevention:** Active Immunization: Vaccines

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*[One will note, that even though the FDA had issued several EUAs, most significantly on February 4, 2021, the NIH continued its section on Convalescent Plasma after was based on the August 23, 2020 EUA announced by President Trump. The FDA Inclusion Criteria of only in Severe COVID-19 affected patients existed from March 24, 2020 until September 2, 2020. Most NIH registered prospective ClinicalTrials existing on September 2, 2020 were based on **That ERRONEOUS Inclusion Criteria**. Note that from October 9, 2020 to February 28, 2021, the NIH hedged its bets by including in the Convalescent Plasma last updated October 9, 2020: ..suggest that convalescent plasma with high antibody titers may be more beneficial than low-titer plasma in nonintubated patients, particularly when administered within 72 hours of COVID-19 diagnosis.*

## Convalescent Plasma

*Last Updated: October 9, 2020*

Plasma from donors who have recovered from COVID-19 may contain antibodies to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) that may help suppress the virus and modify the inflammatory response.<sup>1</sup>

### Recommendation

- There are insufficient data for the COVID-19 Treatment Guidelines Panel (the Panel) to recommend either for or against the use of COVID-19 convalescent plasma for the treatment of COVID-19.

### Rationale for Recommendation

Currently, there are insufficient data from well-controlled, adequately powered, randomized clinical trials to evaluate the efficacy and safety of convalescent plasma for the treatment of COVID-19. However, >70,000 patients in the United States have received COVID-19 convalescent plasma through the Mayo Clinic's Expanded Access Program (EAP), which was designed primarily to provide broad access to investigational convalescent plasma and thus did not include an untreated control arm. Both the Food and Drug Administration (FDA) and the Mayo Clinic performed retrospective, indirect evaluations of efficacy by using the Mayo Clinic EAP data, hypothesizing that patients who received plasma units with higher titers of SARS-CoV-2 neutralizing antibodies would have better clinical outcomes than those who received plasma units with lower antibody titers. The results of their analyses suggest that convalescent plasma with high antibody titers may be more beneficial than low-titer plasma in nonintubated patients, particularly when administered within 72 hours of COVID-19 diagnosis.

The FDA determined that these findings—along with additional data from small randomized and nonrandomized studies, observational cohorts, and animal experiments—met the criteria for Emergency Use Authorization (EUA) issuance.<sup>2,3</sup> Despite meeting the “may be effective” criterion for EUA issuance, the EAP analyses are not sufficient to establish the efficacy or safety of convalescent plasma due to the lack of a randomized, untreated control group and potential confounding. There is no widely available and generally agreed-upon best test for measuring neutralizing antibodies, and the antibody titers of plasma from patients who have recovered from COVID-19 are highly variable. Furthermore, hospitalized patients with COVID-19 may already have SARS-CoV-2 neutralizing antibody titers that are comparable to those of plasma donors, potentially limiting the benefit of convalescent plasma in this patient population.<sup>4,5</sup> Several randomized, placebo-controlled trials of COVID-19 convalescent plasma are ongoing.

The Panel's assessment of the EAP data is consistent with the FDA statements in the convalescent plasma EUA documents.<sup>3,6,7</sup>

**783)** 2021-03-01 van Beusekom M: COVID meta-analysis: No benefit from convalescent plasma. CIDRAP, Center for Infectious Disease Research and Policy, University of Minnesota. <https://www.cidrap.umn.edu/news-perspective/2021/03/covid-meta-analysis-no-benefit-convalescent-plasma>

**784)** 2021-03-02 Hinton DM: Emergency Use Authorization 090 regarding Eli Lilly's bamlanivimab, March 2, 2021. (Now stamped REVOKED—revoked 4-16-2021) <https://www.fda.gov/media/143602/download>

----- September 18, 2023 -----  
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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and Antivirals  
**Prevention:** *Active Immunization:* Vaccines

- 785) 2021-03-02 NIH halts trial of COVID-19 convalescent plasma in emergency department patients with mild symptoms – Study shows the treatment safe, but provides no significant benefit in this group. U.S. National Institute of Health announcement is: <https://www.nih.gov/news-events/news-releases/nih-halts-trial-covid-19-convalescent-plasma-emergency-department-patients-mild-symptoms>

The actual clinic trial, *Convalescent Plasma in Outpatients with COVID-19 (SIREN C3PO)* NCT04355767, was:

<https://clinicaltrials.gov/ct2/show/NCT04355767?term=NCT04355767&draw=2&rank=1>

There are no reported results on the ClinicalTrials website of which the NIH is making its decision to halt the trial. The trial was underpowered where there was no stratification by age and the study was discontinued with recruitment of only half the number of planned patients. This study was run by: **SIREN**, Strategies to Innovate emergency Care Clinical Trials, <https://clic-ctsa.org/node/9426>.

### NIH Announcement to discontinue the trial on March 2, 2021:

Launched in August 2020, the Clinical Trial of COVID-19 Convalescent Plasma of Outpatients ([C3PO\(link is external\)](#)) was being conducted at 47 hospital emergency departments across the United States and had enrolled 511 of the 900 participant recruitment goal. It was specifically looking at the effectiveness of COVID-19 convalescent plasma - blood plasma derived from patients who have recovered from COVID-19 - in adults who came to an emergency department with mild to moderate symptoms they had for a week or less. These patients also had at least one risk factor associated with severe COVID-19, such as obesity, hypertension, diabetes, heart disease, or chronic lung disease, but none were ill enough at the time to be hospitalized.

([C3PO\(link is external\)](#)) <https://siren.network/clinical-trials/c3po>

## **C3PO Clinical Trial of COVID-19 Convalescent Plasma of Outpatients**

Registered with ClinicalTrials.gov: [NCT04355767](https://clinicaltrials.gov/ct2/show/NCT04355767)

{  
<https://clinicaltrials.gov/ct2/show/NCT04355767?term=NCT04355767&draw=2&rank=1>

This is a registered NIH ClinicalTrials.gov

Award Number: 1OT2HL156812-01

**Status:** No new randomizations as of February 25, 2021.

[NIH Press Release \(March 2, 2021\)](#)

- Media inquiries: Refer to [Lenora Johnson, DrPH, MPH](#) and [Mark Sampson](#), and to this press release.

The Clinical Trial of COVID-19 Convalescent Plasma in Outpatients (C3PO) is a multi-center randomized, single blind, two arm, placebo controlled phase III trial with blinded outcome assessment to establish the safety and efficacy of a single dose of convalescent plasma (CP) for preventing the progression from mild to severe COVID-19 illness.

COVID-19 is a respiratory illness caused by the *Severe Acute Respiratory Syndrome Coronavirus 2* (SARS-CoV-2). As of May 1, 2020, over 3 million persons worldwide have been diagnosed with COVID-19 and approximately 250,000 persons have died from this disease. The majority (80%) of cases are categorized as mild, while approximately 15-20% of cases are categorized as severe, with about 5% of all cases progressing into critical illness, characterized by hypoxemic respiratory failure, shock, and end-organ failure. Among the 5% who develop severe disease, as many as 50% die. At present there is no specific therapy for preventing the progression of COVID-19 from mild to severe disease.

Passive antibody therapy using plasma from donors who have been infected and then recovered (convalescent plasma, CP) contains neutralizing antibodies against the infectious agent. Specifically, CP has been used in different respiratory illness epidemics, including the 1918 influenza pandemic, the 2003 SARS-CoV-1 outbreak, and the 2009 H1N1 influenza pandemic. Use of CP for emerging infections has persisted because of strong mechanistic and observational data, but efficacy has yet to be well tested or demonstrated in clinical trials. At this moment, there is no high quality evidence to support the efficacy of CP for treating COVID-19 illness. Conceptually, CP has the highest chance of showing efficacy if used for early treatment of patients at the highest risk for severe disease and mortality.

The overarching goal of this trial is to confirm or refute the role of passive immunization as a safe and efficacious therapy in preventing the progression from mild to severe/critical COVID-19 illness and to understand the immunologic kinetics of anti-SARS-CoV-2 antibodies after passive immunization.

For more information on C3PO and convalescent plasma go to our [In the News page](https://siren.network/clinical-trials/c3po/in-the-news). (<https://siren.network/clinical-trials/c3po/in-the-news> )

## C3PO IN THE NEWS

### March 10, 2021

- Convalescent Plasma Strikes Out As COVID-19 Treatment  
<https://www.npr.org/975365309>

### October 22, 2020

- OHSU researchers say they're having trouble recruiting patients for COVID-19 convalescent plasma trial  
[https://www.kptv.com/ohsu-researchers-say-theyre-having-trouble-recruiting-patients-for-covid-19-convalescent-plasma-trial/video\\_767f3558-10aa-5201-ad47-94322b60070d.html?block\\_id=988363](https://www.kptv.com/ohsu-researchers-say-theyre-having-trouble-recruiting-patients-for-covid-19-convalescent-plasma-trial/video_767f3558-10aa-5201-ad47-94322b60070d.html?block_id=988363)

### September 8, 2020

- NIH clinical trial explores use of convalescent plasma in at-risk outpatients with early COVID-19  
<https://www.nhlbi.nih.gov/news/2020/nih-clinical-trial-explores-use-convalescent-plasma-risk-outpatients-early-covid-19>

### August 25, 2020

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- UF Health enrolls first patients in national COVID-19 study on convalescent blood plasma  
<https://m.ufhealth.org/news/2020/uf-health-enrolls-first-patients-national-covid-19-study-convalescent-blood-plasma>

#### August 19, 2020

- New clinical trial at OHSU tests donated antibodies  
<https://news.ohsu.edu/2020/08/18/new-clinical-trial-at-ohsu-tests-donated-antibodies>

#### August 6, 2020

- Will COVID-19 finally provide an answer on convalescent plasma?  
<https://www.medpagetoday.com/infectiousdisease/covid19/87936>

#### August 3, 2020

- UM and Other Michigan hospitals to treat COVID-19 patients with convalescent plasma.  
<https://www.michiganradio.org/post/um-and-other-michigan-hospitals-treat-covid-19-patients-convalescent-plasma>

#### July 30, 2020

- Michigan hospitals test if plasma from recovering patients can curb COVID-19  
<https://www.bridgemi.com/michigan-health-watch/michigan-hospitals-test-if-plasma-recovering-patients-can-curb-covid-19>
- Researchers at the University of Michigan's Michigan Medicine and three other medical centers were awarded a total of \$7 million from the National Heart, Lung, and Blood Institute (NHLBI) to study convalescent plasma in reducing symptoms of COVID-19 in patients with mild cases, Michigan Medicine announced Thursday.  
<https://www.clickondetroit.com/video/health/2020/07/30/michigan-medicine-7-million-in-funding-for-covid-19-therapy-trial/>
- Michigan Medicine and three other medical centers receive \$7 million COVID-19 outpatient convalescent plasma therapy trial  
<https://www.uofmhealth.org/news/archive/202007/michigan-medicine-and-three-other-medical-centers-receive-7-million-in-funding-for-covid-19-therapy-trial/>
- Trump urges people who have recovered from COVID-19 to donate blood plasma  
<https://www.washingtonpost.com/health/2020/07/30/trump-urges-people-who-have-recovered-covid-19-donate-plasma/>  
<https://www.c-span.org/video/?474383-1/president-trump-roundtable-discussion-donating-plasma>

#### July 29, 2020

- UPMC studying whether convalescent plasma help coronavirus patients with mild symptoms  
<https://pittsburgh.cbslocal.com/2020/07/29/coronavirus-study-convalescent-plasma/>
- COVID-19 trial to study convalescent plasma in outpatient setting

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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*  
**Prevention:** *Active Immunization:* Vaccines

<https://web.musc.edu/about/news-center/2020/07/29/covid19-trial-to-study-convalescent-plasma-in-outpatient-setting>

### March 10, 2021

- Convalescent Plasma Strikes Out As COVID-19 Treatment

<https://www.npr.org/975365309>

2021-03-10 Harris R: Convalescent plasma strikes out as COVID-19 Treatment. NPR, March 10, 2021, 5:01 AM ET

More than half a million Americans have received an experimental treatment for COVID-19 called convalescent plasma. But a year into the pandemic, it's not clear who, if anyone, benefits from it.

That uncertainty highlights the challenges scientists have faced in their attempts to evaluate COVID-19 drugs.

On paper, treatment with convalescent plasma makes good sense. The idea is to take blood plasma from people who have recovered from COVID-19 and infuse it into patients with active infections. The antibodies in the donated plasma, in theory, would help fight the virus.

Based on that idea, last March Dr. Nicole Bouvier at the Icahn School of Medicine at Mount Sinai Hospital in New York decided to give it a try.

She recalls thinking, "we have this new disease that didn't have any known therapies, and convalescent plasma has been used in new epidemic and pandemic diseases," as recently as in an Ebola outbreak in West Africa a few years ago.

She says she was the first doctor to get special permission from the Food and Drug Administration to use it as an experimental treatment.

It was a huge commitment to line up people willing to donate plasma as well as to treat patients themselves, "so it was a big production," she says. "We ultimately screened over 70,000 people" and identified around 20,000 who had high antibody levels in their blood plasma.

Mount Sinai treated more than 1,400 patients, including throughout the height of New York City's nightmarish COVID-19 outbreak last spring. But all the while Bouvier had no idea whether the plasma really worked.

Finally, a couple of weeks ago, she had seen enough data from carefully controlled studies — and decided to stop offering the treatment.

"The straw that broke the camel's back was two very large cohort trials," she says.

The RECOVERY Trial in the United Kingdom had studied more than 10,000 volunteers and found no benefit. Another one called CONCOR-1, run by Canadians, had studied nearly 1,000 patients. It, too, stopped recruiting new patients because doing so would have been futile.

But those studies focused on people sick enough to be in the hospital. Dr. Arturo Casadevall at the Johns Hopkins Bloomberg School of Public Health is one of the prime advocates for convalescent plasma. He says he thinks the treatment needs to be done sooner, in the outpatient setting.

"From the very beginning here at Hopkins we set out to do outpatient trials," he says. "The trials were set up in March [of 2020], however it took many months to get the money to do it." With taxpayer money nowhere to be found, the study ultimately went forward with funding from the billionaire Michael Bloomberg, Casadevall says.

A year later, the study at Hopkins still doesn't have results. And it's not just a question of funding. The entire U.S. medical research system isn't set up to do what's needed to identify new treatments during a pandemic.

[Dr. Derek Angus](#), chair of critical care medicine at the University of Pittsburgh, says that in a public health emergency scientists should be able to evaluate new treatments at hundreds of hospitals, in a matter of months.

"People might roll their eyes and say that's impossible, but that's largely what the United Kingdom has done," Angus says. "For all our capacity in the United States, it's depressing that we can't do a U.S. version."

The U.K. was able to launch its vast study quickly because Britain has a national health system that not only provides treatment but can conduct research. Research in the U.S. is balkanized among universities, drug companies and funders.

"We pride ourselves on having a very federated, independent system," Angus says. "But, gosh, that is very hard to turn on a dime to solve national problems."

To give just one example, a [national network of emergency room physicians](#) got federal funding to treat people with convalescent plasma, in a study named C3PO. Their patients were sick enough to show up in the emergency room, but well enough to go home afterward.

"We should have been able to get this done as quickly as they did in the U.K.," says [Dr. Kevin Schulman](#) at Stanford University. "It was just a much slower process to set up."

Schulman at Stanford was responsible for some of the logistics. And they were a nightmare, he says.

"I said tongue in cheek at some point when we had five patients in our study that we had at least 500 people touch a paper for the five patients we had recruited. And that's the opposite in the UK."

"Some of the contracts for the trial we are still negotiating even today," he adds. "You know, the U.K. didn't have any of that."

The C3PO study recently stopped recruiting patients. It had enrolled about 500 out of a planned 900, but an independent monitoring board concluded that continuing would have been futile.

This further casts doubt on the value of convalescent plasma.

"I don't see any point in offering plasma outside a clinical trial," says Angus from Pitt.

Several trials are ongoing. And there's still a chance that some of them could identify a group of patients, treated at a particular time with a particular concentration of plasma, who would benefit. So Bouvier at Mount Sinai hasn't given up on it completely.

In retrospect, it's understandable why convalescent plasma doesn't help people hospitalized with significant illness, she says. Serious illness is caused primarily by the body's reaction. Respiratory viruses like these don't persist for long. "They're sort of like, 'wham, bam, thank you, ma'am.' And then they're gone," Bouvier says.

"If a study comes along that identifies a population in whom convalescent plasma is useful, we will use it in that population" she says.

And if it does appear to be helpful for people who are early in the course of disease, that raises another question: Would plasma be better than the monoclonal antibody drugs already authorized by the Food and Drug Administration for that purpose and easier to use?

Casadevall at Hopkins argues that plasma might be better, especially if new virus variants can evade the antibody drugs. Antibodies in the plasma of people who have recovered have apparently been successful in controlling whatever virus they encountered, so the treatment actually evolves along with the pandemic.

But to figure out whether convalescent plasma is better than monoclonal antibodies could require another large, time-consuming study in a research system not set up to be nimble.

You can contact NPR Science correspondent Richard Harris at [rharris@npr.org](mailto:rharris@npr.org).

- 786)** 2021-03-04 United States Government / Mayo Clinic: Historical EAP program participation. [EAP=Expanded Access Program = Compassionate Use Program]. March 4, 2021. <https://www.uscovidplasma.org/>
- 787)** 2021-03-05 Woodward A, DeAngelis A: A future COVID-19 vaccine could be squirted up the nose. The nasal spray could stop transmission, especially in kids. <https://www.businessinsider.com/intranasal-covid-19-vaccine-spray-could-stem-spread-2021-3>
- 788)** 2021-03-06-10 Levin J: Remdesivir versus standard of care for severe COVID-19. Conference on Retroviruses and Opportunistic Infections, Boston, MA, March 6-10, 2021. [https://natap.org/2021/CROI/croi\\_197.htm](https://natap.org/2021/CROI/croi_197.htm)
- 789)** 2021-03-6-10 Dougan M, Nirula A, Gottlieb RL, Azizad M, Mocherla B, Chen P, Huhn G, Adams AC, Schade AE, Sabo J, Patel DR, Klekotka P, Shen L, Skovronsky DM, for BLAZE-1 Investigators: Bamlanivimab+Eteseviman for treatment of COVID-19 in high-risk ambulatory patients. Conference on Retroviruses and Opportunistic Infections, Boston, MA, March 6-10, 2021. [https://natap.org/2021/CROI/croi\\_71.htm](https://natap.org/2021/CROI/croi_71.htm)

#### BLAZE-1 Phase 3: Summary

Phase 3 confirms and replicates Phase 2 findings, with 70% reduction in risk of hospitalization ( $p=0.0004$ ), decreased viral load ( $p<0.001$ ), and improved sustained symptom resolution ( $p=0.007$ )

Outcomes consistent with EUA for bamlanivimab alone (71% reduction in risk of hospitalization)

No death due to any cause (Placebo: 10 vs. bamlanivimab + etesevimab together: 0)

Clinically meaningful results reflect the potential of bamlanivimab and etesevimab together in offering strong protection to the most vulnerable patients

Results support the potential for neutralizing monoclonal antibody therapy to reduce mortality, burden on the health care system, and duration of symptomatic disease in infected high-risk individuals

- 790)** 2021-03-06 through 10 Mascolini M: Convalescent plasma has no effect on survival or disease course with severe COVID-19. Conference on Retroviruses and Opportunistic Infections, Boston, MA, March 6-10, 2021. [https://natap.org/2021/CROI/croi\\_70.htm](https://natap.org/2021/CROI/croi_70.htm)

Convalescent plasma from people with COVID-19 did not prolong survival, improve disease course, or affect virologic or immunologic markers of people receiving the plasma during severe disease [1]. Results of this 87-person open-label randomized trial in the Netherlands suggested to the researchers that this therapy "should be studied as early as possible in the disease course or at least preceding the start of an autologous humoral response."

- 791)** 2021-03-06 through 10: (Reported by Jules Levin), Olender S, Walunas TL, Martinez E, Boffito M, Perez KK, Castagna A, Wang S, Goyal P, Ripamonti D, Bernardino JI, Haubrich RH, Chokkalingam AP, Wu G, Diaz-Cuervo H, Brainard D: Remdesivir versus standard of care for severe COVID-19. Conference on retroviruses and opportunistic infections.  
[https://www.natap.org/2021/CROI/croi\\_197.htm](https://www.natap.org/2021/CROI/croi_197.htm)

**Background:** Remdesivir (RDV), a direct-acting nucleotide pro-drug inhibitor of viral RNA-dependent RNA polymerases, was approved by the FDA for the treatment of hospitalized patients (pts) with COVID-19 infection and has been shown to shorten time to recovery and improve clinical outcomes in randomized clinical trials. We present the final Day 28 (D28) analysis of RDV vs standard of care (SOC) (interim Day 14 [D14] analysis published [Olender et al. Clin Infect Dis 2020]).

**Methods:** Final comparative analysis from two studies: a prospective phase 3, randomized study of RDV (RDV cohort) and a real-world retrospective cohort study of SOC (non-RDV cohort). Both studies enrolled pts with SARS-CoV-2 infection confirmed by polymerase chain reaction, who had oxygen saturation  $\geq 94\%$  on room air or required supplemental oxygen and had pulmonary infiltrates. Pts in the RDV cohort were randomized 1:1 to receive IV RDV for 5 or 10 days (200 mg on Day 1 followed by 100 mg/day on Days 2–5 or 2–10), plus SOC; the two randomized dose-groups were combined for analysis. Pts in the non-RDV cohort received SOC as determined by local treatment practices (excluding RDV). Analysis populations were balanced using propensity score (PS) matching. The coprimaries endpoints were D14 clinical recovery (determined using a 7-point ordinal scale) and D28 all-cause mortality. Factors associated with D28 mortality were assessed using a multivariable logistic regression model.

**Results:** After PS matching, baseline characteristics were generally similar in the RDV and non-RDV cohorts; median age 61 years, 63% male, 42% obese, 12% Black, 71% no/low-flow oxygen use, 25% high-flow oxygen, 3% ventilated. Pts in the RDV cohort had significantly higher D14 clinical recovery rates (65% vs 57%) and significantly lower D28 mortality rates (12% vs 16%) compared with the non-RDV cohort (Table). In the multivariable analysis, in addition to RDV use, a lower risk of death at D28 was associated with: younger age; being female; being White (versus being Black/African American); receiving an HIV protease inhibitor prior to baseline; not having cardiovascular disease or COPD; more days of symptoms prior to baseline; and being on room air or low-flow oxygen at baseline (versus being on invasive mechanical ventilation).

**Conclusion:** RDV was associated with significantly higher rates of clinical recovery at Day 14 and lower Day 28 mortality compared with SOC in hospitalized pts with severe SARS-CoV-2 infection.



## Conclusions

- Remdesivir was associated with significantly higher rates of clinical recovery at Day 14 and lower Day 28 all-cause mortality compared with SOC treatment in hospitalized patients with severe COVID-19
- In the subgroup analysis, with limited sample sizes in some groups, a significant mortality benefit could be seen in patients on low-flow oxygen at baseline
- Overall, these data support the use of remdesivir treatment to improve clinical recovery and decrease mortality from severe COVID-19
- Findings are consistent with accumulating evidence supporting the use of remdesivir in patients with severe COVID-19<sup>1–4</sup>
- Remdesivir may help to reduce the burden on hospitals during COVID-19 surges

**792)** 2021-03-08 Winn K: Blood center to phase out CCP donations—Due to strong inventory, decline in COVID-19 hospitalization rate, Blood Center will phase out COVID-19 Convalescent Plasma donations March 26, 2021.  
<https://www.bloodcenter.org/about/news/news-releases/blood-center-to-phase-out-ccp-donations/> ;  
[https://www.bloodcenter.org/webres/File/News%20Releases/CCP%20phase%20out%20March%202021/COVID19%20CCP%20phaseout\\_CICBC.pdf](https://www.bloodcenter.org/webres/File/News%20Releases/CCP%20phase%20out%20March%202021/COVID19%20CCP%20phaseout_CICBC.pdf) ; and  
<https://www.bloodcenter.org/hospitals/patient-services/convalescent-plasma/>

**793)** 2021-03-09 Hinton DM: U.S. Food & Drug Administration Emergency Utilization Authorization (EUA) regarding COVID-19 Convalescent Plasma.  
<https://www.fda.gov/media/141477/download>

Following the August 23, 2020, authorization, additional studies, including randomized, controlled trials, have provided data to further inform the safety and efficacy of COVID-19 use. Based on assessment of these data, **potential clinical benefit of transfusion of COVID-19 convalescent plasma in hospitalized patients with COVID-19 is associated with high titer units administered early in the course of disease.**<sup>6</sup> *Transfusion of COVID-19 convalescent plasma in hospitalized patients late in the course of illness (e.g., following respiratory failure requiring intubation and mechanical ventilation) has not been associated with clinical benefit.* These considerations may be different in patients with suppressed or deficient humoral immunity.

<sup>6</sup>Based on what is known about the typical course of the illness and kinetics of the humoral immune response in COVID-19, for most hospitalized patients, early in the course of disease likely represents prior to respiratory failure requiring intubation and mechanical ventilation. The therapeutic window may be longer when CCP is administered to patients with clinical or laboratory evidence of impaired humoral immunity.

**794)** 2021-03-09 Karamyan VT: Review: Between two storms, vasoactive peptides or bradykinin underlie severity of COVID-19? *Physiol Rep* 2021 Mar 9; 9(5): e14796.  
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7941673/pdf/PHY2-9-e14796.pdf>

## Abstract

----- September 18, 2023 -----  
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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*  
**Prevention:** *Active Immunization:* Vaccines

Coronavirus disease 2019 (COVID-19), caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), continues to be a world-wide pandemic with overwhelming socioeconomic impact. Since inflammation is one of the major causes of COVID-19 complications, the associated molecular mechanisms have been the focus of many studies to better understand this disease and develop improved treatments for patients contracting SARS-CoV-2. Among these, strong emphasis has been placed on pro-inflammatory cytokines, associating severity of COVID-19 with so-called “cytokine storm.” More recently, peptide bradykinin, its dysregulated signaling or “bradykinin storm,” has emerged as a primary mechanism to explain COVID-19-related complications. Unfortunately, this important development may not fully capture the main molecular players that underlie the disease severity. To this end, in this focused review, several lines of evidence are provided to suggest that in addition to bradykinin, two closely related vasoactive peptides, substance P and neurotensin, are also likely to drive microvascular permeability and inflammation, and be responsible for development of COVID-19 pathology. Furthermore, based on published experimental observations, it is postulated that in addition to ACE and neprilysin, peptidase neurolysin (Nln) is also likely to contribute to accumulation of bradykinin, substance P and neurotensin, and progression of the disease. In conclusion, it is proposed that “vasoactive peptide storm” may underlie severity of COVID-19 and that simultaneous inhibition of all three peptidergic systems could be therapeutically more advantageous rather than modulation of any single mechanism alone.

795) 2021-03-10 Association of American Blood Banks (AABB): Regulatory update: FDA Revises CCP EUA, Adds Abbott test. <https://www.aabb.org/news-resources/news/article/2021/03/10/regulatory-update-fda-revises-ccp-eua-adds-roche-test>

796) 2021-03-18 Juneja K, Humeniuk R, Porter D, Cao H, Feng J: Reply to Yan and Muler, “Remdesivir for COVID-19: Why not dose higher?” Antimicrobial Agents and Chemotherapy, 2021 April; 65(4): e1-e3. <https://aac.asm.org/content/aac/65/4/e00085-21.full.pdf>

797) 2021-03-18 Joyner MJ, Carter RE, Senefeld JW, Klassen SA, Mills JR, Johnson PW, Theel ES, Wiffins CC, Bruno KA, Klompas AM, Lesseer ER, Kunze KL, Sexton MA, Diaz Soto JC, Baker SE, Shepherd JRA, van Helmond N, Verdun NC, Marks P, van Buskirk CM, Winters JL, Stubbs JR, Rea RF, Hodge DO, Herasevich V, Whelan ER, Clayburn AJ, Larson KF, Ripoll JG, Andersen KJ, Buras MR, Vogt MNP, Dennis JJ, Regimbal RJ, Bauer PR, Blair JE, Paneth NS, Fairweather DL: Wright RS, Casadevall A: Convalescent plasma antibody levels and the risk of death from Covid-19. N Engl J Med 2021 Mar 18; 384 (11): <https://www.nejm.org/doi/full/10.1056/nejmoa2031893> and <https://www.nejm.org/doi/pdf/10.1056/NEJMoa2031893?articleTools=true>

ORIGINAL ARTICLE

# Convalescent Plasma Antibody Levels and the Risk of Death from Covid-19

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## ABSTRACT

### BACKGROUND

Convalescent plasma has been widely used to treat coronavirus disease 2019 (Covid-19) under the presumption that such plasma contains potentially therapeutic antibodies to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) that can be passively transferred to the plasma recipient. Whether convalescent plasma with high antibody levels rather than low antibody levels is associated with a lower risk of death is unknown.

### METHODS

In a retrospective study based on a U.S. national registry, we determined the anti-SARS-CoV-2 IgG antibody levels in convalescent plasma used to treat hospitalized adults with Covid-19. The primary outcome was death within 30 days after plasma transfusion. Patients who were enrolled through July 4, 2020, and for whom data on anti-SARS-CoV-2 antibody levels in plasma transfusions and on 30-day mortality were available were included in the analysis.

### RESULTS

Of the 3082 patients included in this analysis, death within 30 days after plasma transfusion occurred in 115 of 515 patients (22.3%) in the high-titer group, 549 of 2006 patients (27.4%) in the medium-titer group, and 166 of 561 patients (29.6%) in the low-titer group. The association of anti-SARS-CoV-2 antibody levels with the risk of death from Covid-19 was moderated by mechanical ventilation status. A lower risk of death within 30 days in the high-titer group than in the low-titer group was observed among patients who had not received mechanical ventilation before transfusion (relative risk, 0.66; 95% confidence interval [CI], 0.48 to 0.91), and no effect on the risk of death was observed among patients who had received mechanical ventilation (relative risk, 1.02; 95% CI, 0.78 to 1.32).

### CONCLUSIONS

Among patients hospitalized with Covid-19 who were not receiving mechanical ventilation, transfusion of plasma with higher anti-SARS-CoV-2 IgG antibody levels was associated with a lower risk of death than transfusion of plasma with lower antibody levels. (Funded by the Department of Health and Human Services and others; ClinicalTrials.gov number, NCT04338360.)

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Drs. Joyner, Carter, and Senefeld and Drs. Paneth, Fairweather, Wright, and Casadevall contributed equally to this article.

This article was published on January 13, 2021, at NEJM.org.

N Engl J Med 2021;384:1015-27.

DOI: 10.1056/NEJMoa2011893

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- 798) 2021-03-22 Aleccia JoNel: The hype has faded, but don't count out convalescent plasma in Covid battle. KHN. <https://khn.org/news/article/convalescent-plasma-covid-battle-super-donors/>
- 799) 2021-03-23 FDA: Expanded access. <https://www.fda.gov/news-events/public-health-focus/expanded-access>
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- 802) 2021-03-29 Caplan AI: Placebo Controls: Now??. Arch Immunol Ther Exp (Warsz) 2021 March 29; 69 (1): 9. [https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8006883/pdf/5\\_2021\\_Article\\_612.pdf](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8006883/pdf/5_2021_Article_612.pdf)

September 18, 2023

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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*

**Prevention:** *Active Immunization:* Vaccines

- 803) 2021-03-29 Collinson S: America's pandemic dead deserve accountability after Birx disclosure. CNN politics. <https://www.cnn.com/2021/03/29/politics/coronavirus-deborah-birx-donald-trump-joe-biden/index.html>
- 804) 2021-03-29 Howard J: "All the doctors" working on US coronavirus response received death threats, Birx says. CNN Health. [https://www.cnn.com/health/live-news/covid-pandemic-doctors-cnn-special/h\\_c99768531e3b8232888d7684b37b539f](https://www.cnn.com/health/live-news/covid-pandemic-doctors-cnn-special/h_c99768531e3b8232888d7684b37b539f)
- 805) 2021-03-30. U.S. Food & Drug Administration: Clinical Memorandum, EUA 26382, COVID-19 Convalescent Plasma. <https://web.archive.org/web/20210330024720/https://www.fda.gov/media/141480/download>
- 806) 2021-03-31 Hinton DM: QuickVue At-Home OTC COVID-19 Test EUA210269 <https://www.fda.gov/media/147247/download>
- 807) 2021-04 CDC: Clinical considerations: Myocarditis and pericarditis after receipt of mRNA COVID-19 vaccines among adolescents and young adults. CDC, Vaccines & Immunizations. <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html>
- 808) 2021-04 Spellberg B, Nielsen TB, Casadevall A: Antibodies, Immunity, and COVID-19. JAMA Internal Medicine 2021 April; 181 (4): 460-462. <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2773575>

In summary, a robust and well-designed seroprevalence study using residual serum samples from across the US has found that herd immunity to SARS-Cov-2 is nowhere in sight, even as the COVID-19 pandemic has raged on for a year. The good news is that the limited number of reinfections of SARSCoV-2 to date, and the experience with natural infections with other viruses, suggests that protective immunity to COVID-19 should result, a harbinger for the success of vaccines. The bad news is that, like the 1918 influenza pandemic, achieving herd immunity through natural infections will take years of painful sacrifice that are tallied in numerous deaths, severe longterm health sequelae, and widespread economic disruption and hardship. Let us hope that safe and effective vaccines help avoid the consequences of naturally developing herd immunity to COVID-19, as they have reliably done for so many other respiratory viruses.

- 809) 2021-04-02 Center for Constitutional Rights: Factsheet: U.S. Sanctions on the International Criminal Court. <https://ccrjustice.org/factsheet-us-sanctions-international-criminal-court>

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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*  
**Prevention:** *Active Immunization:* Vaccines

- 810)** 2021-04-06 Liew OW, Ling SSM, Lilyanna S, Zhou Y, Wang LP, Chong JPC, NG YX, Lim AES, Leong ERY, Lin Q, Lim TK, Lin FQ, Ng EMW, Ng TW, Richards AM: Epitope-directed monoclonal antibody production using a mixed antigen cocktail facilitates antibody characterization and validation. *Nature communications biology* 2021; 4 (Article number 441): 1-17. <https://www.nature.com/articles/s42003-021-01965-x> Author correction published 04 May 2021.
- 811)** 2021-04-08 NIH COVID-19 Treatment Guidelines. The COVID-19 Treatment Guidelines Panel's statement on the Emergency Use Authorization of Anti-SARS-CoV-2 monoclonal antibodies for the treatment of COVID-19. **(This is copied verbatim as it is so important)**  
<http://web.archive.org/web/20210417040352/https://www.covid19treatmentguidelines.nih.gov/statement-on-anti-sars-cov-2-monoclonal-antibodies-eua/>

### **The COVID-19 Treatment Guidelines Panel's Statement on the Emergency Use Authorization of Anti-SARS-CoV-2 Monoclonal Antibodies for the Treatment of COVID-19**

*Last Updated: April 8, 2021*

Anti-SARS-CoV-2 monoclonal antibodies that target the SARS-CoV-2 spike protein and block virus entry into cells have been evaluated for the treatment of COVID-19. To date, the Food and Drug Administration (FDA) has issued Emergency Use Authorizations (EUAs) for the following anti-SARS-CoV-2 monoclonal antibodies and combinations: bamlanivimab alone, bamlanivimab plus etesevimab, and casirivimab plus imdevimab.

Data are emerging on the currently available anti-SARS-CoV-2 monoclonal antibodies, including preliminary data from a Phase 3 trial of casirivimab plus imdevimab, and on the in vitro susceptibility of SARS-CoV-2 variants to anti-SARS-CoV-2 monoclonal antibodies. After reviewing the available data, the COVID-19 Treatment Guidelines Panel (the Panel) has updated its recommendations on the use of anti-SARS-CoV-2 monoclonal antibodies in outpatients with mild to moderate COVID-19 who are at high risk of disease progression. In addition, the Panel notes that, because of an increasing number of reports of variants that are resistant to bamlanivimab alone, this product will no longer be distributed by the U.S. government.<sup>1</sup>



Summary Recommendations and Considerations
<ul style="list-style-type: none"> <li>• The COVID-19 Treatment Guidelines Panel (the Panel) recommends using one of the following combination anti-SARS-CoV-2 monoclonal antibodies to treat outpatients with mild to moderate COVID-19 who are at high risk of clinical progression, as defined by the Emergency Use Authorization (EUA) criteria (listed in alphabetical order): <ul style="list-style-type: none"> <li>◦ <del>Bamlanivimab 700 mg plus etesevimab 1,400 mg (AIIa); or</del></li> <li>◦ <del>Casirivimab 1,200 mg plus imdevimab 1,200 mg (AIIa).</del></li> </ul> </li> <li>• Treatment should be started as soon as possible after the patient receives a positive result on a SARS-CoV-2 antigen or nucleic acid amplification test (NAAT) and within 10 days of symptom onset.</li> <li>• There are no comparative data to determine whether there are differences in clinical efficacy or safety between <del>bamlanivimab plus etesevimab and casirivimab plus imdevimab.</del></li> <li>• There are SARS-CoV-2 variants, particularly those that contain the mutation E484K (see below), that reduce the virus' susceptibility to <del>bamlanivimab</del> and, to a lesser extent, <del>casirivimab</del> and <del>etesevimab</del> in vitro; however, the clinical impact of these mutations is not known.</li> <li>• In regions where SARS-CoV-2 variants with reduced in vitro susceptibility to <del>bamlanivimab plus etesevimab</del> are common, some Panel members would preferentially use <del>casirivimab plus imdevimab</del> while acknowledging that it is not known whether in vitro susceptibility data correlate with clinical outcomes.</li> <li>• Because clinical outcome data are limited and there are concerns regarding decreased susceptibility of variants, the Panel <b>recommends against</b> the use of <del>bamlanivimab monotherapy (AIII).</del></li> <li>• If combination products are not available, the use of <del>bamlanivimab monotherapy</del> can be considered for people who meet the EUA criteria on a case-by-case basis.</li> <li>• The Panel <b>recommends against</b> the use of <b>anti-SARS-CoV-2 monoclonal antibodies</b> for patients who are hospitalized because of COVID-19, except in a clinical trial (AIIa). However, their use should be considered for persons with mild to moderate COVID-19 who are hospitalized for a reason other than COVID-19 but who otherwise meet the EUA criteria.</li> </ul>
<p><b>Rating of Recommendations:</b> A = Strong; B = Moderate; C = Optional  <b>Rating of Evidence:</b> I = One or more randomized trials without major limitations; IIa = Other randomized trials or subgroup analyses of randomized trials; IIb = Nonrandomized trials or observational cohort studies; III = Expert opinion</p>

## SARS-CoV-2 Variants of Concern or Interest and Their Susceptibility to Anti-SARS-CoV-2 Monoclonal Antibodies

In laboratory studies, some SARS-CoV-2 variants of concern or interest that harbor certain mutations have markedly reduced susceptibility to bamlanivimab and may have lower sensitivity to etesevimab and casirivimab. However, the impact of these mutations on the clinical response to antibody combinations is uncertain, and the prevalence of these variants in different regions may vary.<sup>2</sup> Of note:

- The B.1.1.7 variant of concern, which is increasing in frequency in the United States, retains in vitro susceptibility to the anti-SARS-CoV-2 monoclonal antibodies that are currently available through EUAs.<sup>3-5</sup>
- The B.1.351 variant of concern has been infrequently detected among the SARS-CoV-2 samples sequenced in the United States to date. This variant includes the E484K mutation, which results in a marked reduction in in vitro susceptibility to bamlanivimab.<sup>4,6,7</sup> In vitro studies suggest that bamlanivimab plus etesevimab has markedly reduced activity against the B.1.351 variant.<sup>3</sup> In vitro studies also suggest that the K417N mutation, which is present in this variant along with the E484K mutation, reduces casirivimab activity, although the combination of casirivimab and imdevimab appears to retain activity.<sup>5</sup>
- The P.1 variant of concern has been infrequently detected among the SARS-CoV-2 samples sequenced in the United States to date. This variant includes the E484K mutation, which results in a marked reduction in in vitro susceptibility to bamlanivimab.<sup>3,7</sup> In vitro studies suggest that bamlanivimab plus etesevimab also has markedly reduced activity against the P.1 variant.<sup>3,6,8</sup> In vitro studies also suggest that the K417T mutation, which is present in this variant along with the E484K mutation, reduces casirivimab activity, although the combination of casirivimab and imdevimab appears to retain activity.<sup>5</sup>
- The B.1.429/B.1.427 variants of concern (also called 20C/CAL.20C) that are circulating in parts of the United States, including California, Arizona, and Nevada, have the L452R mutation. This mutation is associated with a marked reduction in in vitro susceptibility to bamlanivimab. There appears to be a modest in vitro decrease in susceptibility to the combination of bamlanivimab and etesevimab, although the clinical implications of this finding are not known.<sup>3</sup>

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- The B.1.526 variant of interest is circulating in parts of the United States, such as New York. It commonly has the E484K mutation, which is associated with a marked reduction in in vitro susceptibility to bamlanivimab.<sup>3</sup> There appears to also be reduced in vitro susceptibility to the combination of bamlanivimab and etesevimab, although the clinical implications of this finding are not known.<sup>3</sup> In vitro studies suggest that the E484K mutation may reduce casirivimab activity, although the combination of casirivimab and imdevimab appears to retain activity.<sup>5</sup>

Ongoing [population-based genomic surveillance](#) of the types and frequencies of circulating SARS-CoV-2 variants and studies on the susceptibility of different variants to available anti-SARS-CoV-2 monoclonal antibodies will be important in defining the utility of specific monoclonal antibodies in the future.

### **Rationale for Recommending Bamlanivimab Plus Etesevimab**

In the Phase 3 Blocking Viral Attachment and Cell Entry with SARS-CoV-2 Neutralizing Antibodies (BLAZE-1) trial, all the participants met the criteria for being at high risk for progressing to severe COVID-19 and/or hospitalization (as defined in the EUA). A total of 1,035 participants were randomized to receive bamlanivimab 2,800 mg plus etesevimab 2,800 mg (n = 518) or placebo (n = 517).

The median participant age at baseline was 56 years; 31% of the participants were aged ≥65 years. Across the arms, 52% of the participants were women, 87% were White, 29% were Hispanic/Latinx, and 8% were Black or African American. The mean duration of symptoms at study enrollment was 4 days, and 77% of the participants had mild COVID-19.

The primary endpoint was the proportion of participants who had a COVID-19-related hospitalization (defined as ≥24 hours of acute care) or who died from any cause by Day 29. Endpoint events occurred in 11 of 518 participants (2%) in the bamlanivimab plus etesevimab arm and in 36 of 517 participants (7%) in the placebo arm. Compared to the placebo-treated participants, the participants who received bamlanivimab plus etesevimab had a 5% absolute reduction and a 70% relative reduction in COVID-19-related hospitalizations or death from any cause ( $P < 0.001$ ). There were no deaths in the bamlanivimab plus etesevimab arm, and 10 deaths occurred in the placebo arm (10 of 517 participants [2%] died;  $P < 0.001$ ).

Secondary virologic endpoints included SARS-CoV-2 levels on nasopharyngeal (NP) swab assays at different time points. Study participants who received bamlanivimab plus etesevimab had a greater and more rapid decline in virus levels than those who received placebo. The proportion of participants with persistently high viral loads (defined as a SARS-CoV-2 level  $>5.27 \log_{10}$  copies/mL at Day 7) was 10% in the bamlanivimab plus etesevimab arm and 29% in the placebo arm ( $P < 0.000001$ ).

Recommendations for the use of bamlanivimab plus etesevimab should be considered in the context of the following limitations:

- The doses authorized in the EUA are bamlanivimab 700 mg plus etesevimab 1,400 mg, which are different from the doses of bamlanivimab 2,800 mg plus etesevimab 2,800 mg used in the Phase 3 BLAZE-1 study. The lower dose was authorized by the FDA based on preliminary data from BLAZE-4, a double-blind, placebo-controlled, randomized Phase 2 trial.<sup>3</sup> The available data demonstrate that the antiviral activity of bamlanivimab 700 mg plus etesevimab 1,400 mg is similar to that of bamlanivimab 2,800 mg plus etesevimab 2,800 mg.
- The results of the Phase 3 BLAZE-1 trial have not been peer reviewed and published.
- The Panel's recommendations are based on preliminary results only, and the details on the study design, follow-up, and methods are currently limited. When peer-reviewed data for the Phase 3 BLAZE-1 trial become publicly available, the Panel will review the results and update the recommendations if necessary.

### **Rationale for Recommending Casirivimab Plus Imdevimab**

The updated recommendation for the use of casirivimab plus imdevimab is based on Phase 3 results from the [R10933-10987-COV-2067](#) study (the information from this study is currently available only in a press

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release, and there is currently no peer-reviewed preprint or publication).<sup>9,10</sup> This trial compared 1,355 participants who received casirivimab 1,200 mg plus imdevimab 1,200 mg to 1,341 participants who received placebo.

The modified full analysis set (mFAS) included participants who had a positive SARS-CoV-2 polymerase chain reaction result from an NP swab at randomization and one or more risk factors for severe COVID-19. In the mFAS cohort:

- The median participant age at baseline was 50 years. Across the arms, 35% of the participants were Hispanic/Latinx and 5% were Black or African American. The median duration of symptoms prior to enrollment was 3 days.
- COVID-19-related hospitalizations or death from any cause were reported in 18 of 1,355 participants (1.3%) in the casirivimab plus imdevimab arm and 62 of 1,341 participants (4.6%) in the placebo arm ( $P < 0.0001$ ). This represents a 3.3% absolute reduction and a 71% relative reduction in hospitalization or death in the casirivimab plus imdevimab treatment participants.

In the full analysis set, there was 1 death out of 1,849 participants in the casirivimab plus imdevimab arm and 5 deaths out of 1,843 participants in the placebo arm.

Recommendations for casirivimab plus imdevimab should be considered in the context of the following limitations:

- The results of this clinical trial have not been peer reviewed and published.
- The Panel's recommendation is based on preliminary results only, and the details on the study design, follow-up, and methods are limited. When peer-reviewed data for this trial become publicly available, the Panel will review the results and update the recommendations if necessary.

#### **Rationale for Recommending Against the Use of Bamlanivimab Monotherapy**

As noted above, several circulating SARS-CoV-2 variants have mutations that are associated with reduced in vitro susceptibility to certain anti-SARS-CoV-2 monoclonal antibodies that are available through EUAs. In laboratory studies, [some SARS-CoV-2 variants of concern or interest](#) that harbor certain mutations have markedly reduced susceptibility to bamlanivimab alone and possibly lower sensitivity to etesevimab and casirivimab. Reduced in vitro susceptibility to both antibodies in a combination regimen is currently uncommon. Because this field is moving quickly, and real-time testing for variants and mutations is not currently available, it seems prudent to use therapeutic options for which reduced susceptibility to the entire regimen is less likely. Therefore, the Panel **recommends against** the use of **bamlanivimab monotherapy (AIII)**. If combination products are not available, the use of bamlanivimab monotherapy can be considered for people who meet the EUA criteria on a case-by-case basis.

#### **Rationale for Recommending Against the Use of Anti-SARS-CoV-2 Monoclonal Antibodies in Patients Who Are Hospitalized for COVID-19**

The FDA EUAs do not authorize the use of these antibodies in patients who are hospitalized for COVID-19, although their use could be considered for patients who are hospitalized for a non-COVID-19 indication and who meet the EUA criteria for the use of these products. See [Anti-SARS-CoV-2 Monoclonal Antibodies](#) for further discussion of the clinical trial data for hospitalized patients.

Anti-SARS-CoV-2 monoclonal antibodies may be available through expanded access programs for the treatment of immunocompromised patients who are hospitalized because of COVID-19. It is not yet known whether these antibodies provide clinical benefits in people with B-cell immunodeficiency or other immunodeficiencies.

#### **Vaccination**

SARS-CoV-2 vaccination should be deferred for at least 90 days in people who have received anti-SARS-CoV-2 monoclonal antibodies. This is a precautionary measure, as the antibody treatment may interfere with vaccine-induced immune responses.<sup>11</sup>

For people who develop COVID-19 after receiving SARS-CoV-2 vaccination, prior vaccination should not affect treatment decisions, including the use of and timing of treatment with monoclonal antibodies.<sup>11</sup>

### **High-Risk Criteria in the Emergency Use Authorizations for Anti-SARS-CoV-2 Monoclonal Antibodies**

The FDA EUAs for all available anti-SARS-CoV-2 monoclonal antibodies and combinations have the same criteria for use: they allow for the use of the monoclonal antibodies for the treatment of COVID-19 in nonhospitalized adults and children aged  $\geq 12$  years and weighing  $\geq 40$  kg who are at high risk for progressing to severe COVID-19 and/or hospitalization.<sup>3</sup>

High-risk individuals as specified in the EUA are those who meet at least one of the following criteria:

- Body mass index (BMI)  $\geq 35$
- Chronic kidney disease
- Diabetes mellitus
- Immunocompromising condition
- Currently receiving immunosuppressive treatment
- Aged  $\geq 65$  years
- Aged  $\geq 55$  years and have:
  - Cardiovascular disease; *or*
  - Hypertension; *or*
  - Chronic obstructive pulmonary disease/other chronic respiratory disease.
- Aged 12 to 17 years and have:
  - BMI  $\geq 85$ th percentile for their age and gender based on the [Centers for Disease Control and Prevention growth charts](#); *or*
  - Sickle cell disease; *or*
  - Congenital or acquired heart disease; *or*
  - Neurodevelopmental disorders (e.g., cerebral palsy); *or*
  - A medically related technological dependence that is not related to COVID-19 (e.g., tracheostomy, gastrostomy, positive pressure ventilation); *or*
  - Asthma or a reactive airway or other chronic respiratory disease that requires daily medication for control.

**811)** 2021-04-12 Regeneron: Phase 3 prevention trial showed 81% reduced risk of symptomatic SARS-COV-2 infections with subcutaneous administration of REGEN-COV™ (Casirivimab with imdevimab) [https://investor.regeneron.com/news-releases/news-release-details/phase-3-prevention-trial-showed-81-reduced-risk-symptomatic-sars#:~:text=00%20AM%20EDT-.Phase%203%20Prevention%20Trial%20Showed%2081%25%20Reduced%20Risk%20of%20Symptomatic,COV%E2%84%A2%20\(casirivimab%20with%20imdevimab\)](https://investor.regeneron.com/news-releases/news-release-details/phase-3-prevention-trial-showed-81-reduced-risk-symptomatic-sars#:~:text=00%20AM%20EDT-.Phase%203%20Prevention%20Trial%20Showed%2081%25%20Reduced%20Risk%20of%20Symptomatic,COV%E2%84%A2%20(casirivimab%20with%20imdevimab))

**812)** 2021-04-12 Regeneron: Phase 3 Prevention Trial Showed 81% Reduced Risk of Symptomatic SARS-CoV-2 Infections with Subcutaneous Administration of REGEN-COV™ (casirivimab with imdevimab). <https://investor.regeneron.com/node/25016/pdf>

PHASE 3 PREVENTION TRIAL SHOWED 81% REDUCED RISK OF SYMPTOMATIC  
SARS-COV-2 INFECTIONS WITH SUBCUTANEOUS ADMINISTRATION OF REGEN-  
COV™ (CASIRIVIMAB WITH IMDEVIMAB)  
TARRYTOWN, N.Y., April 12, 2021 /PRNewswire/ --

**REGEN-COV rapidly protected household contacts from exposure to SARS-CoV-2 at home, with 72% protection against symptomatic infections in the first week, and 93% in subsequent weeks**

**Among individuals who developed symptomatic infections, REGEN-COV recipients cleared the virus faster and had much shorter symptom duration**

**Regeneron will share data with U.S. FDA and request EUA expansion to include COVID prevention for appropriate populations, using a 1,200 mg subcutaneous dose**

Regeneron Pharmaceuticals, Inc. (NASDAQ: REGN) today announced positive results from a Phase 3 trial (2069A) assessing the ability of REGEN-COV™ (casirivimab with imdevimab) to reduce the risk and burden of COVID-19 infection among household contacts of SARS-CoV-2 infected individuals. The trial, which was jointly run with the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), met its primary and key secondary endpoints, showing that REGEN-COV 1,200 mg administered subcutaneously (SC) reduced the risk of symptomatic infections by 81% in those who were not infected when they entered the trial.

"These data suggest that REGEN-COV can complement widespread vaccination strategies, particularly for those at high risk of infection. Importantly, to date REGEN-COV has been shown *in vitro* to retain its potency against emerging COVID-19 variants of concern," said Myron Cohen, M.D., who leads the monoclonal antibody efforts for the NIH-sponsored COVID Prevention Network (CoVPN) and is Director of the Institute for Global Health & Infectious Diseases at the University of North Carolina at Chapel Hill. "Despite standard precautions to reduce transmission, nearly 10% of unvaccinated individuals living with an infected person developed symptomatic infections if they did not receive REGEN-COV. If authorized, convenient subcutaneous administration of REGEN-COV could help control outbreaks in high-risk settings where individuals have not yet been vaccinated, including individual households and group living settings."

The Phase 3, double-blind, placebo-controlled trial assessed the effect of REGEN-COV on uninfected individuals without anti-SARS-CoV-2 antibodies or any COVID-19 symptoms, who lived in the same household as an individual who tested positive for SARS-CoV-2 within the prior 4 days. The trial enrolled 1,505 people who were not infected with SARS-CoV-2 at baseline and randomized to receive either 1 dose of REGEN-COV (1,200 mg) or placebo, administered as SC injections.

"These findings are very encouraging and suggest that REGEN-COV is highly effective at preventing symptomatic COVID-19 in household contacts of SARS-CoV-2 infected individuals," said Dan H. Barouch, M.D., Ph.D., co-principal investigator of the trial and Director of the Center for Virology and Vaccine Research at Beth Israel Deaconess Medical Center and Professor of Medicine at Harvard Medical School. "The rapid and robust protection, together with the subcutaneous route of administration, support the practical utility of these antibodies in protecting

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against COVID-19 in multiple settings, including after high-risk exposures. These antibodies may be particularly useful in individuals who are not yet vaccinated, and may also have potential in those who are immunosuppressed and may not respond well to vaccines."

On average, individuals treated with REGEN-COV who experienced a symptomatic infection resolved their symptoms in 1 week, compared to 3 weeks with placebo. Infected individuals also cleared the virus faster with REGEN-COV.

"With more than 60,000 Americans continuing to be diagnosed with COVID-19 every day, the REGEN-COV antibody cocktail may help provide immediate protection to unvaccinated people who are exposed to the virus, and we are also working to understand its potential to provide ongoing protection for immunocompromised patients who may not respond well to vaccines," said George D. Yancopoulos, M.D., Ph.D., President and Chief Scientific Officer at Regeneron. "We thank the individuals, investigators and our collaborators involved in the trial, and look forward to rapidly discussing these results with regulatory authorities."

- 813)** 2021-04-12 Regeneron: Phase 3 Prevention Trial Showed 81% Reduced Risk of Symptomatic SARS-CoV-2 Infections with Subcutaneous Administration of REGEN-COV™ (casirivimab with imdevimab). <https://investor.regeneron.com/node/25016/pdf>

- 814)** 2021-04-13 Parkins K: Regeneron's antibody cocktail helps prevent and treat COVID-19 in Phase III studies. <https://www.clinicaltrialsarena.com/news/regenerons-antibody-cocktail-regen-cov-helps-prevent-and-treat-covid-19-in-phase-3-studies/>

- 815)** 2021-04-14: Dutta SS: Early monoclonal antibody therapies beneficial for COVID-19, finds study. News Medical Life Sciences. Apr 14, 2021. <https://www.news-medical.net/news/20210414/Early-monoclonal-antibody-therapies-beneficial-for-COVID-19-finds-study.aspx>

A team of scientists recently conducted a large-scale study at Northwell Health, New York, USA, to evaluate the efficacy of neutralizing monoclonal antibody (MAB) therapies in preventing disease progression among patients with mild to moderate coronavirus disease 2019 (COVID-19). **The findings reveal that the timing of initiating MAB therapy is a crucial factor in determining its efficacy against COVID-19.** The study is currently available on the *medRxiv*\* preprint server.

The medRxiv\* preprint server is as follows: Jarrett M, Licht WB, Bock K, Brown Z, Hirsch JS, Coppa K, Brar R, Bello S, Nash IS: Early experience with neutralizing monoclonal antibody therapy for COVID-19. <https://www.medrxiv.org/content/10.1101/2021.04.09.21255219v1.full.pdf>

- 816)** 2021-04-14 AABB: Toolkit update 04/14/2021 COFVID-19 Convalescent Plasma under emergency use authorization. [https://www.aabb.org/docs/default-source/default-document-library/regulatory/toolkit-for-ccp-under-eua.pdf?sfvrsn=741be857\\_18](https://www.aabb.org/docs/default-source/default-document-library/regulatory/toolkit-for-ccp-under-eua.pdf?sfvrsn=741be857_18)

- 817)** 2021-04-14 Kummer L: Monoclonal antibodies can cut risk of hospitalization, death by 70% in COVID-19 patients. FOX 17, West Michigan.

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<https://www.fox17online.com/news/local-news/kzoo-bc/kalamazoo/monoclonal-antibodies-can-cut-risk-of-hospitalization-death-by-70-in-covid-19-patients>

**818)** 2021-04-16 Linnane C: Eli Lilly asks FDA to revoke EUA for COVID-19 antibody treatment alone to speed transition to combination therapy. April 16, 2021.

<https://www.marketwatch.com/story/eli-lilly-asks-fda-to-revoke-eua-for-covid-antibody-treatment-alone-to-speed-transition-to-combination-therapy-2021-04-16>

**819)** 2021-04-16. Hinton DM: Revocation the EUA for the investigational monoclonal antibody therapy bamlanivimab, *when administered alone...*

<https://www.fda.gov/media/147629/download>

**820)** 2021-04-16. FDA: FDA News release: Coronavirus (COVID-19) Update: FDA revokes Emergency Use Authorization for monoclonal antibody Bamlanivimab.

<https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-revokes-emergency-use-authorization-monoclonal-antibody-bamlanivimab>

**821)** 2021-04-17 Thomas K, Weiland N: The Covid-19 Plasma boom is over. What did we learn from it? *The New York Times* <https://www.nytimes.com/2021/04/17/health/covid-convalescent-plasma.html> finance.yahoo.com/news/ 2020-04-21

[https://finance.yahoo.com/news/covid-19-plasma-boom-over-183252295.html?guccounter=1&guce\\_referrer=aHR0cHM6Ly93d3cuZ29vZ2x1LmNvbS8&guce\\_referrer\\_sig=AQAAANsdGj4POGFCCvZ4XWhRaSO6gMHERUyo72az7g290KE2n3pfeL\\_FY2CdR6-UUXduMuGrujDf64hDPbHQ8FRjIAjEYSxQ5OratcmUofgoxaRiPA3c2ci2KFC6b9YDVJE7BqZPF\\_J0ff14Ften5FlbG400-F-ASWAgroYWYEv7p](https://finance.yahoo.com/news/covid-19-plasma-boom-over-183252295.html?guccounter=1&guce_referrer=aHR0cHM6Ly93d3cuZ29vZ2x1LmNvbS8&guce_referrer_sig=AQAAANsdGj4POGFCCvZ4XWhRaSO6gMHERUyo72az7g290KE2n3pfeL_FY2CdR6-UUXduMuGrujDf64hDPbHQ8FRjIAjEYSxQ5OratcmUofgoxaRiPA3c2ci2KFC6b9YDVJE7BqZPF_J0ff14Ften5FlbG400-F-ASWAgroYWYEv7p)

The Trump administration, buoyed by proponents at elite medical institutions, seized on plasma as a good-news story at a time when there weren't many others. It awarded more than \$800 million to entities involved in its collection and administration, and put Dr. Anthony S. Fauci's face on billboards promoting the treatment.

But by the end of the year, good evidence for convalescent plasma had not materialized, prompting many prestigious medical centers to quietly abandon it. By February, with cases and hospitalizations dropping, demand dipped below what blood banks had stockpiled. In March, the New York Blood Center called Mr. Cohen to cancel his 12th appointment. It didn't need any more plasma.

A year ago, when Americans were dying of Covid at an alarming rate, the federal government made a big bet on plasma. No one knew if the treatment would work, but it seemed biologically plausible and safe, and there wasn't much else to try. All told, more than 722,000 units of plasma were distributed to hospitals thanks to the federal program, which ends this month.

Because the government gave plasma to so many patients outside of a controlled clinical trial, it [took a long time](#) to measure its effectiveness. Eventually, studies did emerge to suggest that under the right conditions, plasma might help. But enough evidence has now accumulated to show that the country's broad, costly plasma campaign had little effect, especially in people whose disease was advanced enough to land them in the hospital.

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In interviews, three federal health officials — Dr. Stephen M. Hahn, the former commissioner of the Food and Drug Administration; Dr. Peter Marks, a top F.D.A. regulator; and Dr. H. Clifford Lane, a clinical director at the National Institutes of Health — acknowledged that the evidence for plasma was limited.

“The data are just not that strong, and it makes it makes it hard, I think, to be enthusiastic about seeing it continue to be used,” Dr. Lane said. The [N.I.H. recently halted](#) an outpatient trial of plasma because of a lack of benefit.

**822)** 2021-04-18 U.S. Food & Drug Administration: Clinical Memorandum, EUA 26382, COVID-19 Convalescent Plasma. <https://web.archive.org/web/20210418170456/https://www.fda.gov/media/141480/download>

**823)** 2021-04-19 U.S. Food & Drug Administration: Clinical Memorandum, EUA 26382, COVID-19 Convalescent Plasma. <https://www.fda.gov/media/141480/download>

**824)** 2021-04-21 NIH COVID-19 Treatment Guidelines: Convalescent Plasma. Last Updated: April 21, 2021. <https://www.covid19treatmentguidelines.nih.gov/therapies/anti-sars-cov-2-antibody-products/convalescent-plasma/>

#### Recommendation

- The COVID-19 Treatment Guidelines Panel (the Panel) **recommends against** the use of **low-titer COVID-19 convalescent plasma** for the treatment of COVID-19 (**AIIB**).
  - Low-titer COVID-19 convalescent plasma is no longer authorized through the convalescent plasma EUA.

#### For Hospitalized Patients With COVID-19 Who Do Not Have Impaired Immunity

- The Panel **recommends against** the use of COVID-19 **convalescent plasma** for the treatment of COVID-19 in mechanically ventilated patients (**AI**).
- The Panel **recommends against** the use of **high-titer COVID-19 convalescent plasma** for the treatment of COVID-19 in hospitalized patients who do not require mechanical ventilation, except in a clinical trial (**AI**).

#### For Hospitalized Patients With COVID-19 Who Have Impaired Immunity

- There is insufficient evidence for the Panel to recommend either for or against the use of high-titer COVID-19 convalescent plasma for the treatment of COVID-19.
  - Observational data including data from case reports, case series, and a retrospective case control study suggest a benefit of COVID-19 convalescent plasma in patients with various primary and secondary humoral immunodeficiencies.<sup>2-16</sup>
  - Several case reports indicate that patients with impaired humoral immunity may experience persistent SARS-CoV-2 viral replication and therefore, may be at risk for developing viral resistance to SARS-CoV-2 antibodies after treatment with COVID-19 convalescent plasma.<sup>17-19</sup>
  - **High-titer convalescent plasma is authorized under the EUA for the treatment of hospitalized patients with COVID-19 and impaired immunity.**

#### For Nonhospitalized Patients With COVID-19

- There is insufficient evidence for the Panel to recommend either for or against the use of high-titer COVID-19 convalescent plasma for the treatment of COVID-19 in patients who are not hospitalized, except in a clinical trial.

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- Convalescent plasma is not authorized for nonhospitalized patients with COVID-19 under the EUA.
- Results from additional adequately powered, well-designed, and well-conducted randomized clinical trials are needed to provide more specific, evidence-based guidance on the role of COVID-19 convalescent plasma in the treatment of nonhospitalized patients with COVID-19

**825)** 2021-04-22 CDC: The Tuskegee Timeline. Last reviewed April 22, 2021.

<https://www.cdc.gov/tuskegee/timeline.htm>

**826)** 2021-04-23 NIH COVID-19 Treatment Guidelines (First copy that eliminated Convalescent Plasma *Last updated October 9, 2020* completely as a therapeutic option.)

<https://web.archive.org/web/20210424024531/https://files.covid19treatmentguidelines.nih.gov/guidelines/covid19treatmentguidelines.pdf>

**827)** 2021-04-25 Auwaerter PG: Coronavirus COVID-19 (SARS-CoV-2). Johns Hopkins ABX Guide, Johns Hopkins Medicine POC-IT Guides.

[https://www.hopkinsguides.com/hopkins/view/Johns\\_Hopkins\\_ABX\\_Guide/540747/all/Coronavirus\\_COVID\\_19\\_SARS\\_CoV\\_2](https://www.hopkinsguides.com/hopkins/view/Johns_Hopkins_ABX_Guide/540747/all/Coronavirus_COVID_19_SARS_CoV_2)

**828)** 2021-04-25 Prior R: Blood banks phase out collecting convalescent plasma, but fear a US blood shortage. 58 WDJT – Milwaukee. <https://www.cbs58.com/news/blood-banks-phase-out-collecting-convalescent-plasma-but-fear-a-us-blood-shortage>

**829)** 2021-04-27 U.S. Treasury Data Lab: How is the federal government funding relief efforts for COVID-19? <https://datalab.usaspending.gov/federal-covid-funding/>

**830)** 2021-04-30 CDC & IDSA: Monoclonal antibodies. COVID-19 Real-time Learning Network. (Last update) <https://www.idsociety.org/covid-19-real-time-learning-network/therapeutics-and-interventions/monoclonal-antibodies/>

**831)** 2021-04-30 Open Society Justice Initiative: Justice initiative settles ICC Executive Order lawsuit with the Biden Administration. <https://www.justiceinitiative.org/newsroom/justice-initiative-settles-icc-executive-order-lawsuit-with-the-biden-administration> Download:

<https://www.justiceinitiative.org/uploads/df5ad29b-deec-45c5-9bab-bb1031a60bcd/osji-v-trump-et-al-4-30-2021.pdf>

**832)** 2021-05 FDA: Fact sheet for health care providers emergency use authorization (EUA) of Bamlanivimab and Etesevimab.

<https://www.fda.gov/media/145802/download#:~:text=The%20U.S.%20Food%20and%20Drug,adults%20and%20pediatric%20patients%2C%20including>

**833)** 2021-05 Klassen SA, Senefeld JW, Johnson PW, Carter RE, Wiggins CC, Shoham S, Grossman BJ, Henderson JP, Musser J, Salazar E, Hartman WR, Bouvier NM, Liu STH, Pirofski L, Baker SE, van Helmond N, Wright RS, Fairweather D, Bruno KA, Wang Z,

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Paneth NS, Casadevall A, Joyner M: The effect of convalescent plasma therapy on COVID-19 patient mortality: Systematic review and meta-analysis. *Mayo Clin Proc*, 2021 May; 96 (5): 1262-1275. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7888247/pdf/main.pdf>

... Importantly, many of the patients enrolled in the studies included in the analyses received convalescent plasma transfusions later in their disease course. In this context, before antibiotics and effective vaccinations, convalescent plasma therapy was widely understood to be most efficacious very early in the course of hospitalizations.<sup>2</sup> <sup>155</sup> As a result, our analysis may underestimate the mortality reduction achievable through early administration of high-titer convalescent plasma for COVID-19.

### Conclusion

This real-time systematic review and meta-analysis of contemporaneous studies highlights that the mortality rate of transfused patients with COVID-19 was lower than that of nontransfused patients with COVID-19 and suggests that **early transfusion of high-titer plasma represents the optimal use scenario to reduce the risk of mortality among patients with COVID-19**. These results favor the efficacy of convalescent plasma as a COVID-19 therapeutic agent.

### Acknowledgments

The authors express their gratitude to the convalescent plasma donors.  
Drs Klassen, Senefeld, Casadevall, and Joyner contributed equally to this article.

- 834) 2021-05-03 Exact Sciences Corp: High sensitivity in a noninvasive **colorectal cancer (CRC) screening option**<sup>1</sup>. In a prospective, head-to-head, point-in-time, 90-site, pivotal study of 10,000 patients **aged 50 to 84 years at average risk for CRC**, published in *The New England Journal of Medicine*, Cologuard demonstrated<sup>1\*</sup>:  
<https://www.cologuardhcp.com/about/clinical-offer>
- 835) 2021-05-04 Reuters Fact Check: Fact Check-Red Cross is accepting plasma from people vaccinated against COVID-19. <https://www.reuters.com/article/factcheck-redcross-vaccinated/fact-check-red-cross-is-accepting-plasma-from-people-vaccinated-against-covid-19-idUSL1N2MR1HU>
- 836) 2021-05-06 Osuchowski MF, Winkler MS, Skirecki T, Cajander S, Shankar-Hari M, Lachmann G, *et al*: The Covid-19 puzzle: deciphering pathophysiology and phenotypes of a new disease entity. *The Lancet, Respiratory Medicine* 2021 Jun; 9(6): 622-642.  
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8102044/pdf/main.pdf>
- 837) 2021-05-07 Regeneron Pharmaceuticals: Safety, Tolerability, and Efficacy of Anti-spike (S) SARS-CoV-2 Monoclonal Antibodies for Hospitalized Adult Patients with COVID-19.  
<https://clinicaltrials.gov/ct2/show/NCT04426695?term=REGN-COV2&cond=Covid19&draw=2&rank=3>

Regeneron Pharmaceuticals has seven studies posted on NIH <https://clinicaltrials.gov> and only one listed as a phase I trial (really, this is representative of the NIH designation of Phase I/II seamless trial to *de facto* avoid PL-115-176). This is legal obfuscation and complete avoidance of the intent of PL-115-176, the Right to Try Act of 2017 (signed by President Trump in 2018), which stipulates that the only requirement that must be met so that a patient can request an

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Investigational Drug or Biologic outside of a clinical trial is that a **Phase I clinical trial be “completed.”** The nominal completion date of NCT04426695 on NIH <https://clinicaltrials.gov> is **May 7, 2021.** Conducting “seamless” Phase 1/2 or 1/2/3 Clinical Trials or Phase 2 or Phase 3 Clinical Trials without completion of a Phase 1 Clinical Trial (safety study) are ethically wrong; a violation of the stated intent of the FDA <https://www.fda.gov/media/72057/download> and NIH <https://grants.nih.gov/grants/guide/notice-files/not-od-16-149.html> standards which are contrary to these agencies’ compliance with statutory mandates of the American people; and I allege that the FDA and the NIH have condoned and facilitated disregard and have violated explicitly that which is stated in PL-155-176, The Right to Try Law – **WITH REGARDS TO ALL INVOLVED PARTIES: THIS IS WRONG!**

**838)** 2021-05-09 Monoclonal antibodies’ cocktail drug can be game changer in Covid treatment: Experts. **The Times of India**, May 9, 2021  
<https://timesofindia.indiatimes.com/city/nagpur/monoclonal-antibodies-cocktail-drug-can-be-game-changer-in-covid-treatment-experts/articleshowprint/82487621.cms>

Nagpur: Experts here are expecting the antibody cocktail drug for Covid-19 developed by pharmaceutical giants Roche and Regeneron to work effectively in home-isolated mild to moderate patients who are at high risk of developing severe illness. The therapy was granted emergency use authorization in India a couple of days ago.

Named ‘REGN-COV2’, the drug is a cocktail of two monoclonal antibodies, Casirivimab and Imdevimab. It is projected to reduce hospitalization by 70%. The drug was tried by former US president Trump after he developed Covid-19 last year.

The therapy is also being looked at something that would help those whose vaccine barrier the virus has breached. It is also expected to be effective on children above 12 years (having body weight more than 40 kg) during the projected third wave when the younger population is likely to be at greater risk of contracting the infection.

Researchers in the western world are strongly pushing for yet another combination of monoclonal antibodies, Eli Lilly’s Bamlanivimab and Etesivimab, which have a strong data outcome on Covid patients. In March, it received US FDA approval as a potential therapy against variants of SARS-COV2.

A triple combination drug — repurposed Interferon Beta-1b with Lopinavir-Ritonavir and Ribavirin — is also projected to help in reducing the viral load and symptoms. The study has found a place in the ‘The Lancet’.

According to senior physician Dr Rajesh Atal, Roche-Regeneron’s REGN-COV2 needs to be given at ‘entry level’ or at an early stage to ensure the spike protein of the SARS-COV2 virus doesn’t attach itself to the cells of the host body. “The drug is to be given on priority to high risk patients like obese people, elderly with comorbidities, diabetic, those ailing having renal issues and so on,” he said.

“The drug is expected to work effectively on patients with pre-exposure or early exposure to the disease,” said Dr Atal and added, “If one monoclonal antibody fails to act on the mutant virus, the other is expected to shoot it down or reduce the risk.”

Infection disease specialist Dr Nitin Shinde, said the cocktail therapy is a good solution for families where one or more members are already infected and others too are showing symptoms. “It’s a well formulated ‘rescue therapy’ which must be administered during the incubation period before the virus gets the better of one,” said Dr Shinde.

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He further said that it should be used prophylactically and prove good for those whose vaccine shield is breached. He hoped the cocktail drug would be effective on children above 12 years of age.

Roche Pharma India's managing director V Simpson Emmanuel has said the outpatient treatment of Covid patients with the therapy would 'complement' the vaccination drive in the country.

Well-known senior physician Dr Nikhil Balankhe said studies have shown that the cocktail drug, if introduced at an early stage, is an excellent combination drug to check severe manifestation of the disease.

Dr Satish Deopujari, a well-known paediatrician, feels the monoclonal antibodies would prove to be the game changer in treatment of Covid-9 in the coming days. "The hybrid antibody (combination of Bamlanivimab-Etesevimab and Casirivimab-Imdevimab) has 85% efficacy as compared to other anti-viral drugs in demand now," he said.

Dr Deopujari warned that with major pharmaceutical players set to import the drug, there could be similar chaos as seen in the case of Remdesivir, Tocilizumab, Itolizumab and Bevacizumab. He said the government and ICMR needs to start planning now to ensure only the needy patients gets the therapy.

"This drug will have high demand in the time to come. Blackmarketing and all kinds of malpractices can't be ruled out. The government needs to start working on a strategy immediately. What happened with Remdesivir shouldn't become the case with monoclonal antibody therapy too," he said.

He said the US is following a scoring pattern. "If you fit the criteria only then you would be given the injection. Similarly, we will have to define a high-risk group. There seems to be no planning yet on how it will be rolled out," said Dr Deopujari.

What is monoclonal antibody therapy

A mouse is given antigen injection having tumor cells

The tumor cells get mixed with the plasma cells already in the body to form hybridoma, a hybrid cell

The hybridoma has only one task, that is to produce antibodies

These antibodies produced in huge quantity are called monoclonal

This antibody immediately kills the novel coronavirus

How it became popular

Former US president Donald Trump was one of the early patients on whom this experimental therapy was used

When it must be given

Ideally, in the first three days or maximum up to first 10 days from onset of Covid symptoms

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Major it is administered during OPD treatment in early stage

No other drug has so far same efficacy, provided it is given in the first 3 or 10 days

Limitations

Recommended only for the high risk group like elderly patients and those with comorbidities

Cost could be Rs1 lakh or 2lakh per dose as doctors/govt will have to triage patients

In India, indiscriminate use can't be ruled out

Benefits

Prevents hospitalization of mild to moderate patients

Three months passive protection to patient

Could be given before travel or attending an event with big gathering

The cost may go down depending on the agreement with the company

At 85%, it has highest efficacy rate as on date and prevents mortality

**839)** 2021-05-10 McLean T: One year after racist statues toppled in Golden Gate Park, new sculptures could be erected. SFGATE <https://www.sfgate.com/bayarea/article/art-installation-replacing-racist-statues-ggp-sf-16165841.php>

**840)** 2021-05-12 Maruhashi T, Higashi Y: Pathophysiological association of endothelial dysfunctions with fatal outcome in COVID-19. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8150852/pdf/ijms-22-05131.pdf>

**841)** 2021-05-14 Recovery Collaborative Group: Convalescent plasma in patients admitted to hospital with COVID-19 (RECOVERY): a randomized controlled, open-label, platform trial. The Lancet 2021 May 29; 397, Issue 10289: 2049-2059.

[https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(21\)00897-7/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)00897-7/fulltext)

Please Note the NIH Clinic Trial NCT04381936

(<https://clinicaltrials.gov/ct2/show/NCT04381936>) had as its Inclusion Criteria: (i) Hospitalised, (ii) SARS-CoV-2 infection (clinically suspected or laboratory confirmed), and (iii) No medical history that might, in the opinion of the attending clinician, put the patient at significant risk if he/she were to participate in the trial.

**842)** 2021-05-15 U.S. Department of Health and Human Services: COMBATCOVID: Monoclonal antibodies for high-risk COVID-19 positive patients. (above title of COMBATCOVID is: "An official website of the United States government") This is the most recent rendition of this DHHS website as the first "digital photograph of this URL" on the Wayback Machine of the Internet Archive is January 15, 2021. <https://web.archive.org/web/20210115190614/https://combatcovid.hhs.gov/i-have-covid-19->

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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*  
**Prevention:** *Active Immunization:* Vaccines

[now/monoclonal-antibodies-high-risk-covid-19-positive-patients](https://web.archive.org/web/20210515023010/https://combatcovid.hhs.gov/i-have-covid-19-now/monoclonal-antibodies-high-risk-covid-19-positive-patients) Below is the initial excerpted paragraphs of that which follows on May 15, 2021.

<https://web.archive.org/web/20210515023010/https://combatcovid.hhs.gov/i-have-covid-19-now/monoclonal-antibodies-high-risk-covid-19-positive-patients> :

If you've tested positive for COVID-19, one of the first questions you may have is, *What can I do to reduce the risk of getting sicker?* The good news is, there are treatments that may reduce that risk. Depending on your age, health history, and how long you've had symptoms of COVID-19, you may qualify for a promising form of treatment for the disease. It's called monoclonal antibody (mAb) treatment.

Some early evidence suggests that mAb treatment can reduce the amount of the SARS-CoV-2 virus (the virus that causes COVID-19) in a person's system. This amount is known as viral load. Having a lower viral load means you may have milder symptoms thereby decreasing the likelihood of you being hospitalized.

mAb treatment may help people who:

- Have a positive COVID-19 test, and had symptoms for 10 days or less, and
- Are at high risk of getting more serious symptoms.

Visit the page "[How Do I Know If I'm High Risk, and What Do I Do Next?](#)" to learn more.

This page describes what mAbs are, how they can prevent mild to moderate symptoms from getting worse, and what to expect if you get mAb treatment.

**843)** 2021-05-18 Executive Summary: COVID-19: Pathophysiology of acute disease. The Lancet, Respiratory Medicine. <https://www.thelancet.com/series/COVID-19-pathophysiology>

**844)** 2021-05-18 Wilt TJ, Kaka AS, MacDonald R, Linskens E, Obley A, Vela K, Duan-Porter W: COVID-19: Remdesivir for Adults – A Living Review. Updated February 2021, Health Services Research & Development Service, U.S. Department of Veterans Affairs. <https://web.archive.org/web/20210602174519/https://www.hsrd.research.va.gov/publications/esp/covid-19-remdesivir.pdf>

**845)** 2021-05-21 Series from the Lancet journals: COVID-19: Pathophysiology of Acute Disease. <https://www.lancet.com/series/COVID-19-pathophysiology>

### Executive Summary

Acute respiratory manifestations are the most common feature of severe COVID-19, but extrapulmonary features of acute disease have also been reported. Emerging evidence indicates that COVID-19 has distinctive pathophysiological features that set the disease apart from respiratory failure of other origins.

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In the first of a Series of four papers, Ignacio Rubio and colleagues provide a comprehensive review of the pathophysiology and phenotypes of COVID-19. The challenges and promise of therapeutically targeting the pleiotropic cytokine interleukin-6 are considered in the second and third papers in the Series. Finally, a fourth paper considers the contributions of viral infection of the alveolar compartment and immunothrombosis of the juxtaposed pulmonary vascular compartment in severe COVID-19. Important questions remain about the clinical complexities and underlying mechanisms of COVID-19. Directions for future research are proposed with the aim of gaining a fuller understanding of the pathophysiology of COVID-19 and subsequently improving management and outcomes for patients.

- 846) 2021-05-24 BETA DATALAB: The Federal Response to COVID-19: How is the federal government funding relief efforts for COVID-19?  
<https://datalab.usaspending.gov/federal-covid-funding/>
- 847) 2021-05-24 Moss C: I'm a vaccinated transplant recipient. I don't have antibodies. Now what? The New York Times, 2021 May 24.  
<https://www.nytimes.com/2021/05/24/opinion/organ-transplant-covid-vaccine.html?referringSource=articleShare>
- 848) 2021-05-24 UPMC: Monoclonal antibodies: A treatment option for COVID-19.  
<https://www.upmc.com/coravirus/monoclonal-antibodies>
- 849) 2021-05-24 U.S. Department of Justice. Office of the Solicitor General.  
<https://www.justice.gov/osg/about-office>
- 850) 2021-05-25 Colbert S: Interview of Francis Collins, M.D., Ph.D. The Late Show with Stephen Colbert. <https://www.youtube.com/watch?app=desktop&v=mi5Uf-Cr73U>
- 851) 2021-05-26 Hinton DM: Emergency Use Authorization 100 regarding Sotrovimab of GlaxoSmithKline LLC. U.S. Food & Drug Administration.  
<https://web.archive.org/web/20210526213011/https://www.fda.gov/media/149532/download>
- 852) 2021-05-26 FDA: Coronavirus (COVID-19) Update: FDA authorizes additional monoclonal antibody for treatment of COVID-19. <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-additional-monoclonal-antibody-treatment-covid-19>

**[This immediate series of references are extremely important and essential to rationalize the errant control over *Passive Immunization* by the FDA and the NIH before the American public over the last 16 months. While it seems the FDA is authorizing another monoclonal antibody in the early treatment arsenal of COVID-19 for the individual, the EUA**

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authorities ***Sotrovimab ONLY as an INVESTIGATIONAL BIOLOGIC*** which is consistent with the EUAs regarding COVID-19 Convalescent Plasma and Regeneron's and Eli Lilly's Monoclonal Antibody Cocktails prohibits the average American from obtaining it. In short, this means (unlike in Japan and India) an individual American who turns COVID-19 positive cannot *de facto* purchase any of these ***Passive Immunization agents*** within 72 hours of diagnosis as they are still ***INVESTIGATIONAL*** --not fully, officially authorized biologics by the FDA and the United States government. The FDA and the NIH continue to avoid the intent of (if not violate Federal Law) PL-115-176, the Right to Try Law of 2018.

*This is an **Ethically Reprehensible methodology** being practiced carte blanche by the agencies of U.S. Department of Health and Human Services of which you oversee, Mr. President: To withhold ***Passive Immunization agents (COVID-19 Convalescent Plasma and Sera and Monoclonal Antibodies and Antibody Cocktails)*** by rationing by federal misinformation and obfuscation is akin to the Tuskegee Syphilis Project of the mid-twentieth century.]*

Today, the U.S. Food and Drug Administration issued an [emergency use authorization \(EUA\)](#) for the investigational monoclonal antibody therapy sotrovimab for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kilograms [about 88 pounds]) with positive results of direct SARS-CoV-2 viral testing and who are at high risk for progression to severe COVID-19, including hospitalization or death. This includes, for example, individuals who are 65 years of age and older or individuals who have certain medical conditions.

The safety and effectiveness of this investigational therapy continues to be evaluated for treatment of COVID-19. Sotrovimab is not authorized for patients who are hospitalized due to COVID-19 or require oxygen therapy due to COVID-19. This treatment has not shown benefit in patients hospitalized due to COVID-19 and monoclonal antibodies may be associated with worse clinical outcomes when administered to hospitalized patients requiring high flow oxygen or mechanical ventilation.

**“With the authorization of this monoclonal antibody treatment, we are providing another option to help keep high-risk patients with COVID-19 out of the hospital,” said Patrizia Cavazzoni, M.D., director of the FDA’s Center for Drug Evaluation and Research. “It is**

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**important to expand the arsenal of monoclonal antibody therapies that are expected to retain activity against the circulating variants of COVID-19 in the United States.”**

Monoclonal antibodies are laboratory-made proteins that mimic the immune system’s ability to fight off harmful antigens such as viruses. Sotrovimab is a monoclonal antibody that is specifically directed against the spike protein of SARS-CoV-2 and is designed to block the virus’ attachment and entry into human cells.

- 853)** 2021-05-26 Chen S: FDA authorizes third COVID antibody therapy treatment. AXIOS <https://www.axios.com/covid-antibody-therapy-fda-authorization-8417a321-2d3e-4350-aaca-d909900a01ef.html>

The U.S. Food and Drugs Administration on Wednesday authorized Vir Biotechnology and GlaxoSmithKline's monoclonal antibody drug treatment for early COVID infections, [the agency said](#).

**Why it matters:** It's the third antibody treatment authorized for patients in the early stages of the disease who are at high risk of developing severe infections. The drug is "expected" to protect against variants, according to the FDA.

- The two companies in March said an interim study showed the drug was highly effective in reducing hospitalizations or death.
- So far, the U.S. has [purchased the treatment](#) directly from manufacturers and offered it to patients through hospitals and health clinics, [Wall Street Journal reports](#).
- Unlike its predecessors, Vir and Glaxo don't have a contract with the federal government, per WSJ. The companies will have to sell the drug commercially.

**What they're saying:** "With the authorization of this monoclonal antibody treatment, we are providing another option to help keep high-risk patients with COVID-19 out of the hospital," Patrizia Cavazzoni, director of the FDA’s Center for Drug Evaluation and Research, said in a statement.

"It is important to expand the arsenal of monoclonal antibody therapies that are expected to retain activity against the circulating variants of COVID-19 in the United States."

- 854)** 2021-05-27 Burris S, Anderson ED, Wagenaar AC: The “Legal Epidemiology” of pandemic control. N Engl J Med 2021 May 27; 384 (21): 1973 – 1975. <https://www.nejm.org/doi/pdf/10.1056/NEJMp2103380?articleTools=true>

- 855)** 2021-05-27 Takvorian SU, Guerra CE, Schpero WL: A hidden opportunity – Medicaid’s role in supporting equitable access to clinical trials. N Engl J Med 2021 May 27; 384 (21): 1975 – 1978. <https://www.nejm.org/doi/pdf/10.1056/NEJMp2101627?articleTools=true>

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- 856)** 2021-05-28 Cohen K: Opinion: If more children had gotten sick from covid, fewer Americans would have died. The Washington Post, May 28, 2021.  
<https://www.washingtonpost.com/opinions/2021/05/28/what-if-covid-killed-more-children/>  
(Gamma Globulin was pooled donor serum).

But one story feels very different. In late June 1953, [Montgomery County undertook a mass inoculation](#) campaign — not with the Salk vaccine, which was still two years from general use, but with gamma globulin, a substance made from blood plasma that was thought to confer some temporary protection against polio.

The campaign began on a Tuesday. The front page of the Montgomery Advertiser carried a boxed announcement: “[White or Black](#). Have You a Child 9 Years Old or Under? Turn to Page 3-B. The Map Shows You Where to Take Your Child. TODAY THRU FRIDAY. For the GG shot that will save it from Crippling Paralysis.” ...

With almost no notice, every single child under 10 was taken to the correct place on the correct day for a treatment that, as the paper explained in a front-page Q&A, didn’t always work but “may provide some protection against paralysis.”

Question 5: “Is GG a cure for polio?” Answer: “No.” And still, 100 percent participation.

So far that year, just 81 Montgomery County residents had contracted polio, and three children had died. And still, 100 percent participation.

Today — with more than [575,000](#) Americans dead — there are vaccine resisters and anti-maskers and politicians who egg them on. That’s already incredible. But if covid victims were mostly children? It would be inconceivable.

- 857)** 2021-05-28 Reuters Fact Check: Fact Check-COVID-19 vaccines don’t strip people of their antibodies; vaccinated individuals can donate blood.  
<https://www.reuters.com/article/factcheck-vaccine-antibodies-plasma/fact-check-covid-19-vaccines-dont-strip-people-of-their-antibodies-vaccinated-individuals-can-donate-blood-idUSL2N2NF0YM>

- 858)** 2021-05-30 Can antibody cocktail used in Trump’s treatment be ‘game changer’ in India’s Covid fight? The Times of India, May 30, 2021, 1-13.  
<https://timesofindia.indiatimes.com/india/how-low-cost-antibody-cocktail-can-be-game-changer-in-indias-covid-fight/articleshow/83089132.cms>

NEW DELHI: Last week, an 84-year-old man from Haryana was administered the "famous" anti-Covid cocktail that was also given to former US President Donald Trump.

The monoclonal antibody cocktail has been touted as a "game-changer" in the fight against [Covid](#). Studies have shown that 80% of patients who took the drug did not need hospitalisation.

The most famous example was Trump himself who tested positive last year. Within, he was back at work.

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However, the cost of the drug remains expensive.

Cipla is marketing the drug in hospitals at an estimated price of Rs 59,000 [~\$800 US] per dose. Only one dose is needed.

**‘A game changer’**

In an interview to ANI, Dr Arvinder S Soin of the Medanta Hospital said that production of the monoclonal antibody drug at a reasonable in India could be a “game changer” for the country.

“If these (Monoclonal antibody drug) are made in large enough quantities at a reasonable price. The monoclonal antibodies could be a game changer for India and the world, and especially for high-risk elderly patients and children. There may come a time of the year when anyone testing positive can have monoclonal antibodies, and to avoid serious disease, we should adopt these early,” Dr. Soin said.

He pointed out that three specific drugs (monoclonal antibodies drug) authorised by the US Food and Drug Administration (FDA) and one by India’s Central Drugs Standard Control Organisation (CDSCO) can ‘nip Covid infection in the bud’.

Dr. Soin said that the drug must be given soon after the patient tests positive, and most certainly in the first week of the infection.

This, can prevent severe disease and deaths.

- 859)** 2021-06-01 Osuchowski MF, Winkler MS, Skirecki T, Cajander S, Shankar-Hari M, Lachmann G, et al. The COVID-19 puzzle: Deciphering pathophysiology and phenotypes of a new disease entity. The Lancet, The Lancet-Respiratory Medicine SERIES, COVID-19: Pathophysiology of acute disease. June 1, 2021; 9(6), P622-642.  
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8102044/pdf/main.pdf>

- 860)** 2021-06-04 FDA: FDA approves drug to treat smallpox. Disease considered eradicated in 1980 but drug development for smallpox is an important component for medical countermeasure response. <https://www.fda.gov/drugs/news-events-human-drugs/fda-approves-drug-treat-smallpox>

- 861)** 2021-06-04 Casadevall A, Dragotakes Q, Johnson PW, Senefeld JW, Klassen SA, Wright RS, Joyner MJ, Paneth N, Carter RE: Convalescent plasma use in the USA was inversely correlated with COVID-19 mortality. eLife 2021; 10e69866.  
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8205484/pdf/elif-69866.pdf>

**Abstract: (Extremely Important!)**

...Changes in the number of hospital admissions, SARS-CoV-2 variants, and age of patients could not explain these findings. The retreat from CCP might have resulted in as many as 29,000 excess deaths from mid-November 2020 to February 2021.

**Conclusions:** A strong inverse correlation between CCP use and mortality per admission in the USA provides population-level evidence consistent with the notion that CCP

reduces mortality in COVID-19 and suggests that the recent decline in usage could have resulted in excess deaths.

- 862) 2021-06-07 Terada M, Kutsuina S, Togano T, Saito S, Kinoshita N, Shimanishi Y, Suzuki T, Miyazato Y, Inada M, Nakamoto T, *et. al.*: How we secured a COVID-19 convalescent plasma procurement scheme in Japan. Transfusion 2021 June; 61 (7): 1998-2007. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8242376/pdf/TRF-9999-0.pdf>

- 863) 2021-06-07 U.S. Food and Drug Administration: FDA grants accelerated approval for Alzheimer's drug. <https://www.fda.gov/news-events/press-announcements/fda-grants-accelerated-approval-alzheimers-drug>

Under the accelerated approval provisions, which provide patients suffering from the disease earlier access to the treatment, the FDA is requiring the company, Biogen, to conduct a new randomized, controlled clinical trial to verify the drug's clinical benefit. If the trial fails to verify clinical benefit, the FDA may initiate proceedings to withdraw approval of the drug.

**BUT on** 2021-06-10: Joseph A: Third member of FDA expert committee resigns over controversial Alzheimer's therapy decision. STATnews  
<https://www.statnews.com/2021/06/10/third-member-of-fda-expert-committee-resigns-over-controversial-alzheimers-therapy-decision/>

- 864) 2021-06-10 Callahan MV, Poznansky MC: The vaccines we have are good. But they could be so much better. The New York Times, June 10, 2021.  
<https://www.nytimes.com/2021/06/10/opinion/covid-vaccine-strategies.html>

- 865) 2021-06-10 California Department of PublicHealth: Monoclonal antibody treatment information for providers and facilities.  
<https://web.archive.org/web/20210826051841/https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/Monoclonal-Antibody-Treatment-Information-for-Providers-and-Facilities.aspx>

- 866) 2021-06-12 Mohanty KK: COVID-19 treatment: Antibody cocktail used to treat Donald Trump is helping patients in India; here's how—Monoclonal antibodies are targeted towards countering a specific antigen, which is nothing but a foreign element that the immune system recognizes to be a threat. Firstpost <https://www.firstpost.com/health/covid-19-treatment-antibody-cocktail-used-to-treat-donald-trump-is-helping-patients-in-india-heres-how-9709411.html>

- 867) 2021-06-15 Steven Colbert: The Late Show with Stephen Colbert on June 15, 2021.  
<https://www.youtube.com/channel/UCMtFAi84ehTSYSE9XoHefig>

New York and California announced the end of virtually all pandemic restrictions after both states achieved 70% vaccination, while businesses nationwide continue to drop performative sanitation measures like excessive disinfecting of surfaces

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- 868) 2021-06-16 Kupferschmidt K: Monoclonal antibodies cut risk of dying from COVID-19—but only in some patients. Science  
<https://www.sciencemag.org/news/2021/06/monoclonal-antibodies-cut-risk-dying-covid-19-only-some-patients>

## Monoclonal antibodies cut risk of dying from COVID-19—but only in some patients

By [Kai Kupferschmidt](#) Jun. 16, 2021, 1:00 AM

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***Science's COVID-19 reporting is supported by the Heising-Simons Foundation.***

The world's largest trial of COVID-19 therapeutics has for the first time produced convincing evidence that a therapy that directly attacks the virus can save hospitalized patients from death. A combination of antibodies called casirivimab and imdevimab, produced by Regeneron, did not lower mortality when all patients in the study were taken together, investigators of the United Kingdom's Recovery trial announced today—but it reduced deaths by one-fifth among those who did not produce antibodies themselves. A paper with the results will be made available on the medRxiv preprint server later today, the researchers say.

“Here you have really the first direct SARS-CoV-2 drug,” says Eric Topol, director of the Scripps Research Translational Institute. Two drugs previously shown to reduce mortality from COVID-19 were developed for other diseases and work by dampening an overactive immune response, which is “kind of an indirect strategy,” Topol says.

But Regeneron's antibodies, which attach to the receptor-binding domain of the spike protein and prevent the virus from entering cells, are expensive and not widely available, and quickly identifying patients that benefit from it may be a challenge.

Researchers have developed several monoclonal antibodies against SARS-CoV-2, with mixed results. Some, including Regeneron's, have shown some positive effects on disease progression in outpatients, but none was demonstrated to save the lives of severely ill patients in the hospital. The Recovery trial started to evaluate Regeneron's cocktail in mid-September 2020. By late May, 9785 patients had been randomly allocated to receive either the usual care in the United Kingdom or the usual care plus a one-time infusion of the two antibodies, a procedure that takes roughly 1 hour.

About one-third of the patients were seronegative when they entered the trial, meaning they did not produce antibodies themselves. That includes people with underlying health conditions that weaken their immune system, but also people who, for unclear reasons, are unable to produce antibodies early on. In this group, 30% of patients given standard care died, versus 24% of those who received the antibody cocktail. That translates to six lives saved for every 100 such patients treated with the drug.

The Regeneron cocktail received a lot of attention when former U.S. President Donald Trump received it during his bout with COVID-19 in October 2020. Although it's not clear whether Trump's immune system produced antibodies, the new results suggest the treatment may have helped save his life, Topol says: “Who knows what might have happened at his age, with his morbid obesity and all the other risk factors that he had.”

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Although it **received an emergency use authorization** from the U.S. Food and Drug Administration in November 2020—and the **U.S. government bought 1.5 million doses**—Regeneron’s therapy has not been widely used in the United States, Topol says. “This is just sitting on shelves,” he says. “I think [the Recovery trial] is going to wake people up as to the benefit.”

But doctors will have to determine which patients fail to produce antibodies. “I think this isn’t a complicated test to run, it just needs to be done,” says Martin Landray of the University of Oxford, one of Recovery’s principal investigators.

A bigger challenge may be cost. “We anticipate, but we don’t know this, that they may be around £1000 or £2000 per treatment,” Recovery co-investigator Peter Horby said at a press conference on Tuesday. That might put the therapy and many similar ones in the pipeline out of reach for most people living in developing countries, which also have far fewer COVID-19 vaccine doses than rich countries. Access to antibody drugs in general has been particularly unequal across the globe, says Lindsay Keir, a pediatrician who co-authored a **Wellcome Trust report on global access to such treatments** released last year. “Antibodies that we have benefited from in high-income countries for 20, 30 years, still aren’t available in many countries,” Keir says.

The inequity is a “scandal,” Horby says. “There really must be an initiative to make these drugs accessible, and that requires two things: They have to be available, which means we have to scale up manufacturing, and they have to be affordable, which means we have to reduce the prices.”

- 869) 2021-06-16 Ellyatt H: Regeneron antibody ‘cocktail’ can save lives in hospitalized Covid patients, study finds. CNBC. <https://www.cnbc.com/2021/06/16/regeneron-antibody-cocktail-can-save-lives-in-hospitalized-covid-patients.html>

## Regeneron antibody ‘cocktail’ can save lives in hospitalized Covid patients, study finds

PUBLISHED WED, JUN 16 2021 5:42 AM EDT UPDATED WED, JUN 16 2021 7:06 AM EDT

### KEY POINTS

- Another potentially life-saving treatment for hospitalized Covid-19 patients has been discovered by researchers at the University of Oxford.
- An antibody combination made by Regeneron reduces the risk of death when given to patients with severe Covid who have not mounted a natural antibody response of their own.
- The study was part of the wider Recovery trial investigating various possible treatments for people hospitalized with coronavirus.

LONDON — Another potentially life-saving treatment for hospitalized Covid-19 patients has been discovered by researchers at the University of Oxford.

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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*  
**Prevention:** *Active Immunization:* Vaccines

The British study — part of the wider Recovery trial investigating various possible treatments for people hospitalized with coronavirus — found that an antibody combination made by [Regeneron](#) reduces the risk of death when given to patients with severe Covid who have not mounted a natural antibody response of their own.

The treatment uses a “cocktail” of two monoclonal antibodies (casirivimab and imdevimab, known as Regen-Cov in the U.S.) that bind specifically to two different sites on the coronavirus spike protein, neutralizing the ability of the virus to infect cells.

Previous studies in nonhospitalized Covid patients have shown that the treatment reduces viral load, shortens the time to the resolution of symptoms, and significantly reduces the risk of hospitalization or death.

But in a small trial in hospitalized patients, preliminary evidence suggested a clinical benefit for patients who had not mounted a natural antibody response of their own (that is, they were seronegative) when they entered the trial.

This latest study is the first trial large enough to determine definitively whether this treatment reduces mortality in patients hospitalized with severe Covid.

The trial, which took place between September and May, involved 9,785 patients hospitalized with Covid.

For patients who were seronegative at the start of the study, the antibody combination significantly reduced their chances of dying by one-fifth compared with those receiving usual care alone (that is, 24% of patients in the antibody combination group died versus 30% of patients in the usual care group).

Thus, for every 100 such patients treated with the antibody combination, there would be six fewer deaths.

As well as reducing the risk of death, for the seronegative patients who received the antibody combination treatment, the duration of hospital stay was four days shorter than for those receiving usual care. The chances of needing a ventilator was also lower.

The treatment had no noticeable beneficial effect on patients who were seropositive at the start of the trial.

The preliminary results from the trial, which will soon be submitted to a leading peer-reviewed medical journal, could determine how Covid patients are treated in future in hospital, one expert noted.

“It means that patients being hospitalised with Covid-19 can be divided into two groups based on whether or not they have made antibodies to the virus,” Fiona Watt, executive chair of the U.K.’s Medical Research Council, said in a statement.

“If they do not have antibodies then treatment with antibody-based drugs to the spike protein can reduce their risk of death and also time spent in hospital. Patients who have made their own antibodies to the virus do not benefit from the new treatment, which is important information given the cost of drugs.”

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Peter Horby, professor of emerging infectious diseases in the Nuffield Department of Medicine at the University of Oxford, and the joint chief investigator for the Recovery trial, described the results as “very exciting.”

“The hope was that by giving a combination of antibodies targeting the SARS-CoV-2 virus we would be able to reduce the worst manifestations of Covid-19. There was, however, great uncertainty about the value of antiviral therapies in late-stage Covid-19 disease. It is wonderful to learn that even in advanced Covid-19 disease, targeting the virus can reduce mortality in patients who have failed to mount an antibody response of their own,” he said in a statement.

The Recovery trial has already made several life-saving discoveries, one being that dexamethasone, a cheap and widely used steroid, was able to save lives among severely ill Covid patients. Last week it published the results of another trial that showed [aspirin did not improve the survival rates for patients hospitalized with Covid](#) who are at an increased risk of blood clots.

- 870) 2021-06-16 Olszewska-Parasiewicz J, Szarpak L, Rogula S, Gasecka A, Szymanska U, Kwiatkowska M, Jaguszewski MJ, Sierpinski R, Zaczynski A, Wierzba W, Kosior DA: Statins in COVID-19 Therapy. *Life* 2021; 11, 565.  
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8234902/pdf/life-11-00565.pdf>

- 871) 2021-06-20 Dickerson J: John Dickerson interviews Scott Gottlieb, M.D. on Face the Nation, June 20, 2021. <https://www.cbsnews.com/news/transcript-scott-gottlieb-face-the-nation-06-20-2021/>

DR. GOTTLIEB: That's right, and I think that this could be a real game changer. **This is a virus that we should be able to drug. The machinery that this virus uses to replicate are things that we've drugged before. It's not a- it's not a very wily virus. It's not a virus that should evade our drug development tools. So I think that we will have a drug that inhibits viral replication.** Pfizer, the company I'm on the board of, is working on one. Merck is working on another one in advanced development. There's a number of other companies also engaged in this pursuit. **I think we will get a drug that inhibits viral replication that could be taken on an outpatient basis and is basically like a Tamiflu for coronavirus that you could take when you first have symptoms, when you first have a diagnosis to prevent the progression to disease.**

- 872) 2021-06-21 Merrilles A: Washington U researchers show COVID-19 treatment often effective against virus variants, in study of rodents. The St. Louis Post-Dispatch  
[https://www.stltoday.com/news/local/metro/washington-u-researchers-show-covid-19-treatment-often-effective-against-virus-variants-in-study-of/article\\_34089b54-7f2e-549a-904d-c4dacbffa031.html](https://www.stltoday.com/news/local/metro/washington-u-researchers-show-covid-19-treatment-often-effective-against-virus-variants-in-study-of/article_34089b54-7f2e-549a-904d-c4dacbffa031.html)

- i. Several monoclonal antibody treatments are currently available in the U.S. under emergency use authorization from the FDA. They are injected as early as possible during a patient's illness, and are often used for patients in more vulnerable groups, who are at higher risk of eventually having severe cases.

- 873)** 2021-06-21 CDC: Multisystem inflammatory syndrome in children (MIS-C) and Adults (MIS-A). <https://www.cdc.gov/mis/about.html>

CDC: 2021-02-24 For Parents: Multisystem inflammatory syndrome in children (MIS-C) associated with COVID-19

- 874)** 2021-06-25 Kansteiner F, Sagonowsky E: Lilly's COVID antibody combo halted nationwide, dealing huge blow to blockbuster program. FIERCE Pharm.

<https://www.fiercepharma.com/pharma/lilly-s-covid-antibody-combo-halted-nationwide-dealing-huge-blow-to-blockbuster-program>

- 875)** 2021-06-28 Bhandari T: COVID-19 vaccines generates immune structures critical for lasting immunity—Vaccines likely strong, persistent immunity to COVID-19. Washington University School of Medicine. <https://medicine.wustl.edu/news/covid-19-vaccine-generates-immune-structures-critical-for-lasting-immunity/>

- 876)** 2021-06-29 wcg FDANews: U.S. Suspends distribution of Eli Lilly COVID-19 Antibody Cocktail. <https://www.fdanews.com/articles/203368-us-suspends-distribution-of-eli-lilly-covid-19-antibody-cocktail>

- 877)** 2021-07-01 Ashbrook M: Only 31 vaccinated Texans have died from COVID-19, DSHS data says. Over 10,000 people have died from the virus in Texas in 2021. The coronavirus vaccine became available to all adults in Texas on March 29.

<https://www.kvue.com/article/news/health/coronavirus/31-covid-19-deaths-in-texas-in-2021-were-of-vaccinated-individuals/269-8c6a7c82-fbde-4b2e-8f4d-694018f17276>

- 878)** 2021-07-08 NIH—COVID-19 Treatment Guidelines, Clinical Management Summary, Last Updated: July 8, 2021, pages 40-42.

<https://files.covid19treatmentguidelines.nih.gov/guidelines/covid19treatmentguidelines.pdf>

## Clinical Management Summary

*Last Updated: July 8, 2021*

Two main processes are thought to drive the pathogenesis of COVID-19. Early in the clinical course, the disease is primarily driven by the replication of SARS-CoV-2. Later in the clinical course, the disease appears to be driven by a dysregulated immune/inflammatory response to SARS-CoV-2 that leads to tissue damage. Based on this understanding, it is anticipated that therapies that directly target SARS-CoV-2 would have the greatest effect early in the course of the disease, while immunosuppressive/anti-inflammatory therapies are likely to be more beneficial in the later stages of COVID-19.

The clinical spectrum of SARS-CoV-2 infection includes asymptomatic or presymptomatic infection and mild, moderate, severe, and critical illness. Figure 1 provides guidance for clinicians on the therapeutic management of nonhospitalized adult patients. This includes patients who do not require hospitalization or supplemental oxygen and those who have been discharged from an

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emergency department or a hospital. Figure 2 provides guidance on the therapeutic management of hospitalized adult patients according to their disease severity and oxygen requirements.

**Figure 1. Therapeutic Management of NonHospitalized Adults with COVID-19**

All outpatients with COVID-19 who enter the health care system should have in-person or telehealth follow-up visits. Symptomatic treatments, including hydration, antipyretics, analgesics, and antitussives, can be initiated as needed.

Patients should be counseled about symptoms that warrant re-evaluation by a health care provider (e.g., new onset dyspnea, worsening dyspnea [particularly dyspnea that occurs while the patient is resting or that interferes with daily activities], mental status changes). Home resources should be assessed before patients are discharged from a clinic, urgent care center, ED, or hospital; outpatients should have access to housing, proper nutrition, a caregiver, and a device that is suitable for telehealth. If patients are discharged while they are still receiving oxygen supplementation, they should receive oximetry monitoring and close follow-up soon after discharge.

PATIENT DISPOSITION	PANEL'S RECOMMENDATIONS
<p><b>Not Requiring Hospitalization or Supplemental Oxygen, As Determined by a Health Care Provider in ED or an In-Person or Telehealth Visit</b></p>	<p>Anti-SARS-CoV-2 monoclonal antibody products are recommended for outpatients with mild to moderate COVID-19 who are at high risk of disease progression, as defined by the EUA criteria (treatments are listed in alphabetical order):<sup>a</sup></p> <ul style="list-style-type: none"> <li>• Casirivimab plus imdevimab; or</li> <li>• Sotrovimab</li> </ul> <p>At this time, the Panel <b>recommends against</b> the use of <b>bamlanivimab plus etesevimab</b> in these patients due to an increase in the proportion of potentially resistant variants (AIII).<sup>a</sup> See text for details.</p> <p>The Panel <b>recommends against</b> the use of <b>dexamethasone</b> or <b>other systemic glucocorticoids</b> in the absence of another indication (AIII).<sup>b</sup></p>
<p><b>Discharged From Hospital Inpatient Setting in Stable Condition and Does Not Require Supplemental Oxygen</b></p>	<p>The Panel <b>recommends against</b> continuing the use of <b>remdesivir (AIIa)</b>, <b>dexamethasone (AIIa)</b>, or <b>baricitinib (AIIa)</b> after hospital discharge.</p>
<p><b>Discharged From Hospital Inpatient Setting and Requires Supplemental Oxygen</b></p> <p><i>For those who are stable enough for discharge but who still require oxygen<sup>c</sup></i></p>	<p>There is insufficient evidence to recommend either for or against the continued use of remdesivir, dexamethasone, and/or baricitinib. Review the text below when considering the use of any of these agents after hospital discharge.</p>
<p><b>Discharged From ED Despite New or Increasing Need for Supplemental Oxygen</b></p> <p><i>When hospital resources are limited, inpatient admission is not possible, and close follow-up is ensured<sup>d</sup></i></p>	<p>The Panel recommends using <b>dexamethasone</b> 6 mg PO once daily for the duration of supplemental oxygen (dexamethasone use should not exceed 10 days) with careful monitoring for adverse events (BIII).</p> <p>There is insufficient evidence to recommend either for or against the use of remdesivir. When considering the use of remdesivir, review the text below for further discussion.</p> <p>The Panel <b>recommends against</b> the use of <b>baricitinib</b> in this setting, except in a clinical trial (AIII).</p>
<p><b>Rating of Recommendations:</b> A = Strong; B = Moderate; C = Optional  <b>Rating of Evidence:</b> I = One or more randomized trials without major limitations; IIa = Other randomized trials or subgroup analyses of randomized trials; IIb = Nonrandomized trials or observational cohort studies; III = Expert opinion</p>	

<sup>a</sup> In laboratory studies, some SARS-CoV-2 variants of concern or interest harbor certain mutations that are associated with reduced susceptibility to certain agents. Some regimens may be preferred in certain settings based on the degree of reduced susceptibility and the prevalence of these variants in a given region. See Anti-SARS-CoV-2 Monoclonal Antibodies and the Panel's statement on the EUAs for anti-SARS-CoV-2 monoclonal antibodies for more information. Updates on the distribution of bamlanivimab plus etesevimab are available on the HHS Bamlanivimab/Etesevimab website.

<sup>b</sup> There is currently a lack of safety and efficacy data on the use of these agents in outpatients with COVID-19; using systemic glucocorticoids in this setting may cause harm.

<sup>c</sup> These individuals should receive oximetry monitoring and close follow-up through telehealth, visiting nurse services, or in-person clinic visits.

<sup>d</sup> In cases where resources (e.g., inpatient beds, staff members) are scarce, it may be necessary to discharge an adult patient and provide an advanced level of home care, including supplemental oxygen (whether patients are receiving oxygen at home for the first time or are increasing their baseline oxygen requirements), pulse oximetry, and close follow-up through visiting nurse services, telehealth, or in-person clinic visits.

**Key:** ED = emergency department; EUA = Emergency Use Authorization; HHS = Department of Health and Human Services; the Panel = the COVID-19 Treatment Guidelines Panel; PO = orally

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**Prevention:** Active Immunization: Vaccines

**Figure 2. Therapeutic Management of Hospitalized Adults With COVID-19 Based on Disease Severity**

DISEASE SEVERITY	PANEL'S RECOMMENDATIONS
Hospitalized but Does Not Require Supplemental Oxygen	<p>The Panel <b>recommends against</b> the use of <b>dexamethasone (AIIa)</b> or other <b>corticosteroids (AIII)</b>.<sup>a</sup></p> <p>There is insufficient evidence to recommend either for or against the routine use of remdesivir. For patients who are at high risk of disease progression, the use of remdesivir may be appropriate.</p>
Hospitalized and Requires Supplemental Oxygen	<p>Use one of the following options:</p> <ul style="list-style-type: none"> <li>• <b>Remdesivir<sup>b,c</sup></b> (e.g., for patients who require minimal supplemental oxygen) (<b>BIIa</b>)</li> <li>• <b>Dexamethasone<sup>d</sup> plus remdesivir<sup>b,c</sup></b> (e.g., for patients who require increasing amounts of supplemental oxygen) (<b>BIII</b>)</li> <li>• <b>Dexamethasone<sup>d</sup></b> (when combination therapy with remdesivir cannot be used or is not available) (<b>BI</b>)</li> </ul>
Hospitalized and Requires Oxygen Delivery Through a High-Flow Device or Noninvasive Ventilation	<p>Use one of the following options:</p> <ul style="list-style-type: none"> <li>• <b>Dexamethasone<sup>d</sup></b> (<b>AI</b>)</li> <li>• <b>Dexamethasone<sup>d</sup> plus remdesivir<sup>b,c</sup></b> (<b>BIII</b>)</li> </ul> <p>For patients who were recently hospitalized<sup>a</sup> with rapidly increasing oxygen needs and systemic inflammation:</p> <ul style="list-style-type: none"> <li>• Add either <b>baricitinib<sup>e,g</sup></b> (<b>BIIa</b>) or <b>tocilizumab<sup>h</sup></b> (<b>BIIa</b>) to one of the two options above</li> </ul>
Hospitalized and Requires IMV or ECMO	<p>For most patients:</p> <ul style="list-style-type: none"> <li>• <b>Dexamethasone<sup>d,i</sup></b> (<b>AI</b>)</li> </ul> <p>For patients who are within 24 hours of admission to the ICU:</p> <ul style="list-style-type: none"> <li>• <b>Dexamethasone<sup>d,i</sup> plus tocilizumab<sup>h</sup></b> (<b>BIIa</b>)</li> </ul>
<p><b>Rating of Recommendations:</b> A = Strong; B = Moderate; C = Optional  <b>Rating of Evidence:</b> I = One or more randomized trials without major limitations; IIa = Other randomized trials or subgroup analyses of randomized trials; IIb = Nonrandomized trials or observational cohort studies; III = Expert opinion</p>	
<p><sup>a</sup> Patients who are receiving dexamethasone or another corticosteroid for other indications should continue therapy for their underlying conditions as directed by their health care provider.</p> <p><sup>b</sup> The dose for remdesivir is 200 mg IV for one dose, followed by remdesivir 100 mg IV once daily for 4 days or until hospital discharge (unless the patient is in a health care setting that can provide acute care that is similar to inpatient hospital care). Treatment duration may be extended to up to 10 days if there is no substantial clinical improvement by Day 5.</p> <p><sup>c</sup> For patients who are receiving remdesivir but progress to requiring oxygen through a high-flow device, noninvasive ventilation, IMV, or ECMO, remdesivir should be continued until the treatment course is completed.</p> <p><sup>d</sup> The dose for dexamethasone is 6 mg IV or PO once daily for 10 days or until hospital discharge. If dexamethasone is not available, equivalent doses of other corticosteroids (e.g., prednisone, methylprednisolone, hydrocortisone) may be used. See the Corticosteroids section for more information.</p> <p><sup>e</sup> For example, within 3 days of hospital admission. See the Interleukin-6 Inhibitors section for more information.</p> <p><sup>f</sup> As there are no studies that directly compare using baricitinib and tocilizumab as treatments for COVID-19, the Panel has insufficient evidence to recommend one drug over the other. Treatment decisions should be based on local guidance, drug availability, and patient comorbidities.</p> <p><sup>g</sup> The dose for baricitinib is 4 mg PO once daily for 14 days or until hospital discharge (refer to Table 4c for dose modifications for patients with renal impairment). Baricitinib should be used in combination with steroids (with or without remdesivir). The combination of baricitinib plus tocilizumab has not been studied, and the Panel <b>recommends against</b> the use of this combination, except in a clinical trial (<b>AIII</b>).</p> <p><sup>h</sup> The dose for tocilizumab is 8 mg/kg of actual body weight (up to 800 mg) administered as a single IV dose. The combination of tocilizumab plus baricitinib has not been studied, and the use of this combination should be avoided outside of a clinical trial. See the Interleukin-6 Inhibitors section for more information.</p> <p><sup>i</sup> The combination of <b>dexamethasone plus remdesivir</b> may be considered for patients who have recently been intubated (<b>CIII</b>). The Panel <b>recommends against</b> the use of remdesivir monotherapy in these patients.</p> <p><b>Key:</b> ECMO = extracorporeal membrane oxygenation; ICU = intensive care unit; IMV = invasive mechanical ventilation; IV = intravenous; the Panel = the COVID-19 Treatment Guidelines Panel; PO = orally</p>	

**879)** 2021-07-11 Cowen L: Race to a cure for ALS. CBS Sunday Morning, July 11, 2021.  
[https://www.cbs.com/shows/cbs-sunday-morning/video/FTG9i0qA5cvpjj\\_a7wvKYtaxvqT4PUtT/race-to-a-cure-for-als/](https://www.cbs.com/shows/cbs-sunday-morning/video/FTG9i0qA5cvpjj_a7wvKYtaxvqT4PUtT/race-to-a-cure-for-als/)

**880)** 2021-07-12 Quinn M: Fauci says it is “inexplicable” some Americans aren’t getting vaccinated despite data. <https://www.cbsnews.com/news/covid-vaccines-fauci-data/>  
Transcript: <https://www.cbsnews.com/news/transcript-dr-anthony-fauci-on-face-the-nation-july-11-2021/>

DR. FAUCI: Well, I think maybe all of the above, you know, it is almost inexplicable why people, when they see the data in front of them that they don't get vaccinated. We have a Delta variant that you mentioned, John, that is easily transmissible much more easily and readily and efficiently from person to person than the other viruses, the other variants that we've dealt with. That's the first thing. The second thing, the data that's hitting you right between the eyes is that ninety nine point five percent of all the deaths to COVID-19 are in unvaccinated people.

**881)** 2021-07-15 Ohl ME, Miller DR, Lund BC: Association of Remdesivir treatment with survival and length of hospital stay among US veterans hospitalized with COVID-19.  
<https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2781959>

**882)** 2021-07-15 Turner JS, Kim W, Kalaidina E, Goss CW, Rauseo AM, Schmitz AJ, Hansen L, Haile A, Klebert MK, Pusic I, O'Halloran JA, Presti RM, Ellebedy AH: SARS-CoV-2 infection induces long-lived bone marrow plasma cell in humans. Nature 2021 Jul 15; 595: 421-425. <https://www.nature.com/articles/s41586-021-03647-4.pdf>

**883)** 2021-07-16 Cohen A: Unvaccinated Americans drive up COVID-19 hospitalization rates—About 97 percent of hospitalizations are tied to unvaccinated people.  
<https://www.rollcall.com/2021/07/16/unvaccinated-americans-drive-up-covid-19-hospitalization-rates/>

**884)** 2021-07-17 Achenbach J: In this summer of covid freedom, disease experts warn: ‘The world needs a reality check’. The Washington Post, July 17, 2021.  
[https://www.washingtonpost.com/health/in-this-summer-of-covid-freedom-disease-experts-warn-the-world-needs-a-reality-check/2021/07/17/895be6e8-e58c-11eb-b722-89ea0dde7771\\_story.html](https://www.washingtonpost.com/health/in-this-summer-of-covid-freedom-disease-experts-warn-the-world-needs-a-reality-check/2021/07/17/895be6e8-e58c-11eb-b722-89ea0dde7771_story.html)

**885)** 2021-07-19 Cohen K: Opinion: The two numbers that could get people to take the vaccine. The Washington Post.  
<https://www.washingtonpost.com/opinions/2021/07/19/covid-death-numbers-vaccinated-vs-unvaccinated/>

We’re talking history-making, world-saving efficacy. A new [Yale study](#) estimates that, by the end of June, [coronavirus](#) vaccines had prevented approximately 279,000 deaths in the United States alone. Rochelle Walensky, director of the Centers for Disease Control and Prevention, said that in

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states with low vaccination rates more than [99 percent](#) of covid-19 deaths over the past six months were among unvaccinated people.

**886)** 2021-07-20 Nikkei staff writers: Japan approves COVID antibody cocktail used to treat Trump – Roche unit's offering holds promise as a tool against worsening cases. NIKKEI Asia, July 20, 2021 <https://asia.nikkei.com/Spotlight/Coronavirus/Japan-approves-COVID-antibody-cocktail-used-to-treat-Trump>

**887)** 2021-07-25 Lumen: Microbiology, vaccines.  
<https://courses.lumenlearning.com/microbiology/chapter/vaccines/>

**888)** 2021-07-26 Pirahanchi Y, Sharma S: Physiology, Bradykinin. NCBI Bookshelf.  
<https://www.ncbi.nlm.nih.gov/books/NBK537187/?report=printable>

**889)** 2021-07-28 Bergwerk M, Gonen T, Lustig Y, Amit S, Lipsitch M, Cohen C, Mandelboim, Gal Levin E, Rubin C, Indenbaum V, Tal I, Zavitan M, Zucherman N, Bar-Chaim A, Kreiss Y, Regev-Yochay G: Covid-19 breakthrough infections in vaccinated health care workers. New Engl J Med, NEJM.ORG July 28, 2021.  
<https://www.nejm.org/doi/pdf/10.1056/NEJMoa2109072?articleTools=true>

#### ABSTRACT

##### RESULTS

Among 1497 fully vaccinated health care workers for whom RT-PCR data were available, 39 SARS-CoV-2 breakthrough infections were documented. Neutralizing antibody titers in case patients during the peri-infection period were lower than those in matched uninfected controls (case-to-control ratio, 0.361; 95% confidence interval, 0.165 to 0.787). Higher peri-infection neutralizing antibody titers were associated with lower infectivity (higher Ct values). Most breakthrough cases were mild or asymptomatic, although 19% had persistent symptoms (>6 weeks). The B.1.1.7 (alpha) variant was found in 85% of samples tested. A total of 74% of case patients had a high viral load (Ct value, <30) at some point during their infection; however, of these patients, only 17 (59%) had a positive result on concurrent Ag-RDT. No secondary infections were documented.

##### CONCLUSIONS

Among fully vaccinated health care workers, the occurrence of breakthrough infections with SARS-CoV-2 was correlated with neutralizing antibody titers during the peri-infection period. Most breakthrough infections were mild or asymptomatic, although persistent symptoms did occur.

**890)** 2021-07-28 Abutaleb Y, Achenbach J, Diamond D, Taylor A: CDC urges vaccinated people in covid hot spots to resume wearing masks indoors. The Washington Post, July 28, 2021. <https://www.washingtonpost.com/health/2021/07/27/cdc-masks-guidance-indoors/>

**891)** 2021-07-28 Powell K, Prasad V: The Noble lies of COVID-19 – Do we want public health officials to report facts and uncertainties transparently? Or do we want them to shape information to influence the public to take specific actions? SLATE  
<https://slate.com/technology/2021/07/noble-lies-covid-fauci-cdc-masks.html>

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**Prevention:** *Active Immunization:* Vaccines

- 892) 2021-07-30 Hinton DM: EUA 091 authorizing *Post-Exposure Prophylaxis*.

<https://www.regeneron.com/downloads/treatment-covid19-eua-fda-letter.pdf>

<https://www.fda.gov/media/145610/download>

REGEN-COV may only be used in adult and pediatric individuals (12 years of age and older weighting at least 40 kg) for post-exposure prophylaxis of COVID-19 in individuals who are at high risk for progression to severe COVID-19, including hospitalization or deaths, and are:

Not fully vaccinated **or** who are not expected to mount an adequate immune response to complete SARS-CoV-2 vaccination (for example, individuals with immunocompromising conditions including those taking immunosuppressive medications **and**

have been exposed to an individual infected with SARS-CoV-2 consistent with close contact criteria per Centers for Disease control and Prevention **or** who are at high risk of exposure to an individual infected with SARS-CoV-2 because of occurrence of SARS-CoV-2 infection in other individuals in the same institutional setting (for example, nursing homes, prisons).

...only be used in adult and pediatric individuals (12 years of age and older weighting at least 40 kg) for post-exposure prophylaxis of COVID-19 in individuals who are at high risk for progression to severe COVID-19, including hospitalization or deaths, and are

- 893) 2021-08 Mayo Clinic: Different types of COVID-19 vaccines: How they work.

<https://web.archive.org/web/20210806124201/https://www.mayoclinic.org/diseases-conditions/coronavirus/in-depth/different-types-of-covid-19-vaccines/art-20506465>

- 894) 2021-08-02 Shammas B, Suliman A, Pietsch B: U.S. hits Biden's vaccination goal a month late, with 70% of adults receiving at least one shot. The Washington Post, August 2, 2021. <https://www.seattletimes.com/nation-world/u-s-hits-bidens-vaccination-goal-a-month-late-with-70-of-adults-receiving-at-least-one-shot/>

- 895) 2021-08-02 Reality Check team, BBC News: Coronavirus: Was US money used to fund risky research in China? BBC News. <https://www.bbc.com/news/57932699>

- 896) 2021-08-05 NIH—COVID-19 Treatment Guidelines, Clinical Management Summary, Last Updated: August 5, 2021, pages 40-42.

<https://files.covid19treatmentguidelines.nih.gov/guidelines/covid19treatmentguidelines.pdf>

## Clinical Management Summary

*Last Updated: July 8, 2021*

Two main processes are thought to drive the pathogenesis of COVID-19. Early in the clinical course, the disease is primarily driven by the replication of SARS-CoV-2. Later in the clinical course, the disease appears to be driven by a dysregulated immune/inflammatory response to SARS-CoV-2 that leads to tissue damage. Based on this understanding, it is anticipated that therapies that directly target SARS-CoV-2 would have the greatest effect early in the course of the disease, while immunosuppressive/anti-inflammatory therapies are likely to be more beneficial in the later stages of COVID-19.

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**Prevention:** *Active Immunization:* Vaccines



The clinical spectrum of SARS-CoV-2 infection includes asymptomatic or presymptomatic infection and mild, moderate, severe, and critical illness. Figure 1 provides guidance for clinicians on the therapeutic management of nonhospitalized adult patients. This includes patients who do not require hospitalization or supplemental oxygen and those who have been discharged from an emergency department or a hospital. Figure 2 provides guidance on the therapeutic management of hospitalized adult patients according to their disease severity and oxygen requirements.

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<https://digitalcommons.wayne.edu/cgi/viewcontent.cgi?article=1075&context=honorstheses>
- 899) 2021-08-10 FDA authorizes REGEN-COV monoclonal antibody therapy for post-exposure prophylaxis (prevention) for COVID-19. *Prophylaxis with REGEN-COV is not a substitute for vaccination against COVID-19.* <https://www.fda.gov/drugs/drug-safety-and-availability/fda-authorizes-regen-cov-monoclonal-antibody-therapy-post-exposure-prophylaxis-prevention-covid-19>
- 900) 2021-08-10 Mayo Clinic Staff: COVID-19 vaccines for kids: What you need to know. <https://www.mayoclinic.org/diseases-conditions/coronavirus/in-depth/covid-19-vaccines-for-kids/art-20513332>
- 901) 2021-08-10 LaVito A, Levin J, Maglione F: Delta forces hospitals across U.S. to ration scarce ICU beds. <https://news.bloomberglaw.com/health-law-and-business/delta-strains-hospitals-across-u-s-as-unvaccinated-fill-icus>
- 902) 2021-08-10 Lancaster University: Intranasal vaccine offers promise to block COVID-19 where it starts. ScienceDaily.  
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- 904) 2021-08-12 Weiland N, Robbins R: As virus cases surge, Biden administration encourages more use of antibody treatments. The New York Times.  
<https://www.nytimes.com/2021/08/12/us/politics/biden-covid-monoclonal-antibodies.html>
- 905) 2021-08-16 Goldberg C: Antibody cocktails to treat Covid take off as delta surges. Bloomberg <https://www.bloomberg.com/news/articles/2021-08-16/once-rare-antibody-cocktails-to-treat-covid-take-off-amid-delta>

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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*  
**Prevention:** *Active Immunization:* Vaccines

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- 907) 2021-08-17 Benen S: As COVID slams Fla., DeSantis focuses on treatment, not prevention. <https://www.msnbc.com/rachel-maddow-show/covid-slams-fla-desantis-focuses-treatment-not-prevention-n1276981>
- 908) 2021-08-17 CDC: COVID-19: Children & Teens. [https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/adolescents.html?s\\_cid=11583:cdc%20covid%20vaccine%20kids:sem.ga:p:RG:GM:gen:PTN.Grants:FY21](https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/adolescents.html?s_cid=11583:cdc%20covid%20vaccine%20kids:sem.ga:p:RG:GM:gen:PTN.Grants:FY21)
- 909) 2021-08-18 Whitely J: Why is Gov. Abbott receiving Regeneron treatment if he has no COVID-19 symptoms? Gov. Abbott remained quiet on his first full day in quarantine in the governor's mansion. Abbott's office did not provide an update on his condition. Texas News <https://www.wfaa.com/article/news/local/texas/why-gov-abbott-receiving-regeneron-treatment-no-covid-19-symptoms/287-22b6ea37-9784-42a2-8e54-03235f451882>
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- 911) 2021-08-18 Centers for Medicare & Medicaid Services (CMS.gov): Monoclonal Antibody COVID-19 Infusion. <https://web.archive.org/web/20210821064228/https://www.cms.gov/medicare/covid-19/monoclonal-antibody-covid-19-infusion>
- 912) 2021-08-18 Carlson R: NIH study shows no significant benefit of convalescent plasma for COVID-19 outpatients with early symptoms. National Institutes of Health. <https://www.nih.gov/news-events/news-releases/nih-study-shows-no-significant-benefit-convalescent-plasma-covid-19-outpatients-early-symptoms>
- 913) 2021-08-19 Sick-Samuels AC, Messina A: COVID-19 Vaccine: What parents need to know. Hopkins Medicine <https://www.hopkinsmedicine.org/health/conditions-and-diseases/coronavirus/covid19-vaccine-what-parents-need-to-know>
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- 915) 2021-08-20 Carlson R: Convalescent plasma failed to deliver significant benefits for high-risk COVID-19 outpatients. <https://www.precisionvaccinations.com/convalescent-plasma-failed-deliver-significant-benefits-high-risk-covid-19-outpatients>
- 916) 2021-08-20 Edwards E: As cases surge, antibody treatments can slow hospitalizations, but vaccines are best. Monoclonal antibodies, when given early, can help prevent severe illness in high-risk patients. <https://www.nbcnews.com/health/health-news/cases-surge-antibody-treatments-can-slow-hospitalizations-vaccines-are-best-n1277286>
- 917) 2021-08-20 FDA: Fact sheet for health care providers Emergency Use Authorization (EUA) of REGEN-COV™ (casirivimab and imdevimab). <https://web.archive.org/web/20210820092946/https://www.fda.gov/media/145611/download>  
On page 25 of 56:
- Obesity or being overweight (for example, BMI >25 kg/m<sup>2</sup> ....
- A BMI>25 kg/m<sup>2</sup> which is greater than two-thirds of the Adult population of America!**
- Monaco K: Over 73% of U.S. adults overweight or obese—Obesity rate up by half since 1999-2000, NHANES data indicate; nearly 10% severely obese. MedPage Today, December 11, 2020. <https://www.medpagetoday.com/primarycare/obesity/90142> or <https://web.archive.org/web/20210820161313/https://www.medpagetoday.com/primarycare/obesity/90142>
- 918) 2021-08-20 Mishra S: Evidence mounts that people with breakthrough infections can spread Delta easily—A new study finds that this dominant variant can grow in the noses of vaccinated people as strongly as in unvaccinated people. National Geographic, Science | Coronavirus Coverage <https://www.nationalgeographic.com/science/article/evidence-mounts-that-people-with-breakthrough-infections-can-spread-delta-easily>
- [More than 93.8 percent of the U.S.](#) is at substantial or high level of risk for community transmission of SARS-CoV-2, according to the Centers for Disease Control and Prevention (CDC). CDC [defines an area to be at high risk](#) when either the number of new cases in a county exceeds 100 per 100,000 persons, or more than 10 percent of COVID-19 tests come back positive in the past seven days. In those areas, CDC recommends wearing a mask indoors in public to maximize protection from the Delta variant and prevent spreading it to others.
- 919) 2021-08-20 UPMC: Monoclonal Antibodies: A treatment option for COVID-19. Printed out 8/20/2021. <https://www.upmc.com/coronavirus/monoclonal-antibodies>
- 920) 2021-08-23 Malarkey MA, Gruber MF: Biologics License Application approval for Comirnaty, Pfizer-BioNTech COVID-19 mRNA Vaccine: BL 125742/0. <https://www.fda.gov/media/151710/download>
- 921) 2021-08-23 Hinton DM: Reissues the EUA for the Pfizer COVID-19 Vaccine to clarify the issue of the BLA 125742/0 approval. <https://www.fda.gov/media/150386/download>

On August 23, 2021, FDA approved the biologics license application (BLA) submitted by BIONTech Manufacturing GmbH for COMIRNATY (COVID-19 Vaccine, mRNA) for active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 16 years of age and older.

On August 23, 2021, having concluded that revising this EUA is appropriate to protect the public health or safety under section 564(g)(2) of the Act, FDA is reissuing the August 12, 2021 letter of authorization in its entirety with revisions incorporated to clarify that the EUA will remain in place for the Pfizer-BioNTech COVID-19 vaccine for the previously-authorized indication and uses, and to authorize use of COMIRNATY (COVID-19 Vaccine, mRNA) under this EUA for certain uses that are not included in the approved BLA. In addition, the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) was revised to provide update language regarding warnings and precautions related to myocarditis and pericarditis. The Fact Sheet for Recipients and Caregivers was updated as the Vaccine Information Fact Sheet for COVID-19 Vaccine and information about the FDA-licensed vaccine, COMIRNATY (COVID-19 Vaccine, mRNA).

Pfizer-BioNTech COVID-19 Vaccine contains a nucleoside-modified messenger RNA (modRNA) encoding the viral spike (S) glycoprotein of SARS-CoV-2 formulated in lipid particles. COMIRNATY (COVID-19 Vaccine, mRNA) is the same formulation as the Pfizer-BioNTech COVID-19 Vaccine and can be used interchangeably with the Pfizer-BioNTech COVID-19 Vaccine to provide the COVID-19 vaccination series.<sup>8</sup>

- 922)** 2021-08-23 FDA: FDA approves first COVID-19 Vaccine. (Marketed as Comirnaty) <https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine>  
FDA: Comirnaty and Pfizer-BioNTech COVID-19 Vaccine <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/comirnaty-and-pfizer-biontech-covid-19-vaccine>

Example NBC report regarding this approval with Dr. Fauci response.  
<https://www.nbc.com/today/video/today-in-30-august-24-dr-anthony-fauci-coronavirus-and-the-classroom/345221659>

- 923)** 2021-08-24 Pouwels KB, Pritchard E, Matthews PC, Stoesser N, Eyre DW, Vihta KD, House T, Hay J, Bell JI, Newton JN, Farrar J, Crook D, Cook D, Rourke E, Studley R, Peto T, Diamond I, Walker S, the COVID-19 Infection Survey Team. Impact of Delta on viral burden and vaccine effectiveness against new SARS-CoV-2 infections in the UK. medRxiv <https://www.medrxiv.org/content/10.1101/2021.08.18.21262237v1>

- 924)** 2021-08-24 Zients J, Walensky R, **Fauci A**, Murthy V: Press briefing by White House COVID-19 response team and public health officials. Transcript: <https://www.whitehouse.gov/briefing-room/press-briefings/2021/08/24/press-briefing-by-white-house-covid-19-response-team-and-public-health-officials-51/>

DR. FAUCI: Thank you very much, Dr. Walensky. I'd like to spend the next couple of minutes in addressing a **much-underutilized intervention for COVID-19, and that is the use of monoclonal antibodies for the TREATMENT and PREVENTION of SARS-CoV-2 infection and COVID-19 disease.**

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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*  
**Prevention:** *Active Immunization:* Vaccines

Next slide.

For those not totally familiar with this, monoclonal antibody is an antibody that's produced by a single clone of B cells or a cell line, and consists of identical antibody molecules that can actually be produced in the in-vitro situation in unlimited quantities.

Next slide.

If you look at the virion on the upper-left part of the slide and you look up the blown-up spike protein — the red molecule on the right upper panel — **when you talk about polyclonal antibodies, which result from infection or vaccination, it's a group of antibodies against every aspect of the spike protein, which is the good news. However, the concentration and the affinity of those antibodies can be markedly improved if you get a single cloned antibody — hence the word "monoclonal" — that's against the very specific part of the spike protein that can have a major effect in prevention and treatment.**

Next slide.

So, let's look at what we have. We have three anti-SARS-CoV-2 monoclonal antibody products that have currently had Emergency Use Authorization from the FDA. And the EUAs here are for adults and children 12 years of age and older who weigh at least 88 pounds.

There are three of them. There's the Lilly product — the bamlanivimab plus etesevimab. There's the Regeneron project — product, referred to as REGEN-COV. And then there's the GSK and Vir product. Each of these products targets the spike protein of SARS-CoV-2.

Next slide.

So, you can do an indication for these antibodies that are twofold. The first is to treat infection with SARS-CoV-2.

Next slide.

And in this regard, clinical trials have demonstrated that early treatment with anti-SARS-CoV-2 monoclonal antibodies can reduce the risk of COVID-19 hospitalization or death by 70 to 85 percent.

It is important to emphasize that this must be done early in infection and not wait, of course, until a person is sick enough to be hospitalized. That's when you get the best effect.

And again, being an underutilized intervention, we want people out there, including physicians, as well as potential patients, to realize the advantage of this very effective way of treating early infection.

Next slide.

Now, if you look at the people who should benefit from this, this is a list from the FDA and the NIH treatment guidelines about all of the people who may have significant benefit from this type of therapy if given early in their infection.

I'm not going to go through each and every one of them, but as you can see, there are a number of

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conditions on this slide that could benefit from the monoclonal antibody treatment after infection.

Next slide.

But there's also the benefit of prevention using monoclonal antibodies.

Next slide.

And we know now that the FDA, just a couple of weeks ago, authorized the Regeneron monoclonal antibody for post-exposure prophylaxis, namely for the prevention of COVID-19 after someone has been exposed to a documented case of SARS-CoV-2.

And even now — and I won't show the data because of lack of time — there are now studies in pre-exposure prophylaxis, as well as other studies in treatment.

So, I'll have on the last slide — next slide — the treatment guidelines panel. We can give you all the information, and it's accessible on the website shown here. And for physicians, patients, and others who want to know how you can get monoclonal antibodies administered, this is the call center and this is the online way to approach it.

So, bottom line is: This is a very effective intervention for COVID-19. It is underutilized, and we recommend strongly that we utilize this to its fullest.

YouTube (Fauci slide show: 10:22 – 15:27 minutes in presentation)

<https://www.youtube.com/watch?v=AZNP05w2cxU>

- 925)** 2021-08-25 NIH/NLM: MedlinePlus—Trusted Health Information for You. Gene Therapy and Other Advances. Chapter 6: What are mRNA vaccines and how do they work? [https://web.archive.org/web/20210825084027mp\\_/https://medlineplus.gov/download/genetics/understanding/therapy.pdf](https://web.archive.org/web/20210825084027mp_/https://medlineplus.gov/download/genetics/understanding/therapy.pdf)

- 926)** 2021-08-26. Salter J: New Missouri sites announced for monoclonal antibody infusion treatments. <https://www.ksdk.com/article/news/health/coronavirus/new-missouri-sites-monoclonal-antibody-infusion-treatments/63-2905c735-0e9e-41f0-99df-75ed44cd063e>

- 927)** 2021-08-26 Senator Ron Johnson: Letter to FDA Acting Commission Janet Woodcock, M.D. U.S. Senate. <https://www.hsgac.senate.gov/imo/media/doc/2016-09-19%20RHJ%20to%20FDA%20Califf%20declined%20invite.pdf>

In the letter that reissued the EUA for the Pfizer-BioNTech COVID-19 vaccine, the FDA stated that Comirnaty and the Pfizer-BioNTech COVID-19 vaccines are “legally distinct with certain differences that do not impact safety or effectiveness.”<sup>4</sup> That statement, together with the fact that the FDA issued two distinct letters – one extending the EUA for the vaccine used in the U.S. and the other granting the FDA approval of the Comirnaty vaccine used in Europe and other countries – has caused a great deal of confusion.

- 928)** 2021-08-27 Hinton DM: ID NOW COVID-19 EUA200074 for Abbott Diagnostics qualitative detection of nucleic acid of SARS-CoV-2 virus.  
<https://www.fda.gov/media/136522/download>
- 929)** 2021-08-27 Centers for Medicare & Medicaid Services (CMS.gov): Monoclonal antibody COVID-19 infusion. <https://www.cms.gov/medicare/covid-19/monoclonal-antibody-covid-19-infusion>
- 930)** 2021-08-27 CDC, COVID-19: CDC recommends use of Johnson & Johnson's Janssen COVID-19 vaccine resume. <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/JJUpdate.html>
- 931)** 2021-08-30 KMOV.COM Staff: Monoclonal antibody treatment center coming to St. Louis City. [https://www.kmov.com/news/monoclonal-antibody-treatment-center-coming-to-st-louis-city/article\\_e1f92a34-090b-11ec-aba6-db344cba84e7.html](https://www.kmov.com/news/monoclonal-antibody-treatment-center-coming-to-st-louis-city/article_e1f92a34-090b-11ec-aba6-db344cba84e7.html)
- 932)** 2021-08-30 Hick JL, Hanfling D, Wynia MK, Toner E: Crisis standards of care and COVID-19: What did we learn? How do we ensure equity? What should we do? Nam.edu/Perspectives. <https://nam.edu/crisis-standards-of-care-and-covid-19-what-did-we-learn-how-do-we-ensure-equity-what-should-we-do/>
- 933)** 2021-08-30 Wilt TJ, Kaka AS, MacDonald R, Linskens E, Obley A, Vela K, Duan-Porter W: COVID-19: Remdesivir for Adults – A Living Review. U.S. Department of Veterans Affairs, Veterans Health Administration, Health Services Research & Development Service (HSR&D), Evidence Synthesis Program.  
<https://www.hsrd.research.va.gov/publications/esp/covid-19-remdesivir.pdf> Unable to be accessed on 1/23/2022. **But** with the Wayback Machine, one can access a 35 page document of May 18, 2021 and a 33 page document of February 17, 2021 published by VHA Health Services Research & Development Service (HSR&D). Wilt TJ, Kaka AS, McDonald R, Linskens E, Obley A, Vela K, Duan-Porter W: COVID-19: Remdesivir for Adults – A living Review, Updated May 2021. VHA Health Services Research & Development Service (HSR&D).  
<https://web.archive.org/web/20210602174519/https://www.hsrd.research.va.gov/publications/esp/covid-19-remdesivir.pdf>

## WHAT'S NEW

### Updated May 18, 2021

Search current as of May 10, 2021

Next update expected August 31, 2021 This update revises findings from our second update of February 2021 and includes a literature search through May 10, 2021. One new small, single-center, high risk of bias RCT compared a 5-day course of remdesivir to standard of care (SC) in adults hospitalized with severe COVID-19. In per-protocol analysis, remdesivir as compared to SC did not reduce mortality, need for invasive mechanical ventilation, or frequency of adverse events. Results align with previous conclusions that remdesivir probably results in little to no difference in mortality or subsequent need for ventilation. Given the study's high risk of bias, we did not include it in aggregate certainty of evidence. ratings. Our

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original conclusions regarding certainty and strength of evidence on effectiveness of remdesivir for adults with COVID-19 remain unchanged.

WHAT DID WE KNOW? Our prior VA-ESP report of 5 randomized trials (RCTs) concluded that in hospitalized adults with COVID-19, remdesivir probably results in little to no reduction in mortality, a moderate increase in percent recovered, and a moderate reduction in serious adverse events.1 Effects on mortality may vary by initial respiratory support but not by other patient or disease factors. Effect on hospital length of stay or percent hospitalized is mixed (3 RCTs), in part due to continued hospitalization while administering remdesivir. For adults not receiving mechanical ventilation or extracorporeal membrane oxygenation, a 5-day course of remdesivir may provide benefits over, and fewer harms than, a 10-day course. Trials excluded pregnant women or those with severe hepatic or renal dysfunction. On October 22, 2020 the FDA approved remdesivir for patients over age 12 and weighing more than 40kg hospitalized with COVID-19.2 The FDA has noted side effects of remdesivir.3 Remdesivir is the only drug so far to receive federal approval for COVID-19. WHAT IS NEW? Updated: 05/18/2021 Search current as of 5/10/2021 This update adds 1 RCT (high risk of bias), giving a total of 6 included RCTs,4-9 and revises findings from our second update of February 2021.1 The new RCT was a small single-center study from India that compared a 5-day course of remdesivir to standard of care (SC) in adults hospitalized with severe COVID-19.9 In per-protocol analysis, remdesivir as compared to SC did not reduce mortality, need for invasive mechanical ventilation, or frequency of adverse events. Results align with previous conclusions that remdesivir probably results in little to no difference in mortality or subsequent need for ventilation. Given the study's high risk of bias, we did not include it in aggregate certainty of evidence. Summary of conclusions and updated findings are detailed in Table 1. WHAT DO WE CONCLUDE? The results of this new study did not change our prior conclusion that overall, a 10-day remdesivir course probably results in little to no reduction in mortality (4 RCTs). Remdesivir may result in a small reduction in proportion on mechanical ventilation (3 RCTs) but probably results in little to no difference in new need for ventilation versus SC (1 RCT). Remdesivir probably results in a moderate increase in percent recovered, a moderate decrease in serious adverse events, and may result in a large reduction in time to recovery. Effect on hospital length of stay or percent remaining hospitalized is mixed. Effects on mortality may vary by initial respiratory support but not by other patient or disease factors including symptom or COVID-19: Remdesivir for Adults (updated May 2021) Evidence Synthesis Program 2 hospitalization duration, age, sex, race/ethnicity, smoking status, comorbidities, geographic location, or corticosteroid use. Remdesivir may increase mortality in those already on invasive mechanical ventilation or extracorporeal membrane oxygenation (ECMO). Recovery effects may not vary by age, sex, symptom duration, or disease severity. Remdesivir probably reduces serious adverse effects that include measures of COVID-19 disease progression. Compared with 10 days, a 5-day remdesivir course may reduce mortality and need for mechanical ventilation, may increase recovery and/or clinical improvement by small to moderate amounts, and may reduce serious adverse events among patients not requiring mechanical ventilation at baseline. Drug costs would be lower. Pregnant women, children under age 12, and individuals with severe renal and hepatic dysfunction have been excluded from studies. Caution and monitoring are indicated if remdesivir is used in these individuals. The FDA notes that remdesivir side effects include elevated liver enzymes and allergic reactions (which may include changes in blood pressure and heart rate, low blood oxygen level, fever, shortness of breath, wheezing, swelling (eg, lips, around eyes, under the skin), rash, nausea, sweating, or shivering)

## WHAT'S NEW

### Updated February 17, 2021

Search current as of February 8, 2021

Next update expected April 2021 This update revises findings from our first update of November 2020 and includes a literature search through February 8, 2021. No new trials were identified. However, the largest RCT on remdesivir – Solidarity – is newly available as a peer-reviewed publication (previously available as

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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*  
**Prevention:** *Active Immunization:* Vaccines

a non-peer review preprint). Our updated findings include new analyses and data on recovery/improvement, need for ventilation, hospital length of stay, and percentage of patients hospitalized between days 7- 14. We also provide new mortality analyses by subgroups.

WHAT DID WE KNOW? Our prior VA-ESP report of 5 randomized trials (RCTs) concluded that in hospitalized adults with COVID-19, remdesivir probably results in little to no reduction in mortality, a moderate increase in percent recovered, and a moderate reduction in serious adverse events. Effect on hospital length of stay or percent hospitalized is mixed (3 RCTs) in part due to continued hospitalization while administering remdesivir.<sup>1</sup> For adults not receiving mechanical ventilation or extracorporeal membrane oxygenation, a 5-day course of remdesivir may provide similar benefits to, and fewer harms than, a 10-day course. Trials excluded pregnant women or those with severe hepatic or renal dysfunction. On October 22, 2020 the FDA approved remdesivir for patients over age 12 and weighing more than 40kg hospitalized with COVID-19.<sup>2</sup> Remdesivir is the only drug so far to receive federal approval for COVID-19. WHAT IS NEW? Updated: 02/17/2021 Search current as of 2/8/2021 This update revises findings from our first update of November 2020 and also includes a literature search through February 8, 2021.<sup>3</sup> This update includes 5 RCTs,<sup>4-8</sup> similar to the prior report. However, the largest RCT on remdesivir – Solidarity – is newly available as a peerreviewed publication (previously available as a non-peer review pre-print).<sup>5</sup> Our updated findings include new analyses and data on recovery/improvement, need for ventilation, hospital length of stay, and percentage of patients hospitalized between days 7-14. We also provide new mortality analyses by subgroups defined by baseline respiratory support requirements: no oxygen, requiring supplemental oxygen but not ventilation, and requiring ventilation. Summary of conclusions and updated findings are detailed in Table 1. WHAT DO WE CONCLUDE? Overall, a 10-day remdesivir course probably results in little to no reduction in mortality (4 RCTs). Remdesivir may result in a small reduction in proportion on mechanical ventilation (3 RCTs) but probably results in little to no difference in new need for ventilation versus standard care (1 RCT). Remdesivir probably results in a moderate increase in percent recovered, a moderate decrease in serious adverse events, and may result in a large reduction in time to recovery. Effect on hospital length of stay or percent remaining hospitalized is mixed. Effects on mortality may vary by initial respiratory support but not by other patient or disease factors including: symptom or hospitalization duration, age, sex, race/ethnicity, smoking status, comorbidities, geographic location, or corticosteroid use. Remdesivir may increase mortality in those already on invasive mechanical ventilation or extracorporeal membrane oxygenation COVID-19: Remdesivir for Adults (updated Feb 2021) Evidence Synthesis Program 2 (ECMO). Recovery effects may not vary by age, sex, symptom duration, or disease severity. Remdesivir probably reduces serious adverse effects that include measures of COVID-19 disease progression. Compared with 10 days, a 5-day remdesivir course may reduce mortality and need for mechanical ventilation, and may increase recovery and/or clinical improvement by small to moderate amounts, and may reduce serious adverse events among patients not requiring mechanical ventilation at baseline. Drug costs would be lower. Pregnant women, children under age 12, and individuals with severe renal and hepatic dysfunction have been excluded from studies. Caution and monitoring are indicated if remdesivir is used in these individuals. The FDA notes that remdesivir side effects include elevated liver enzymes and allergic reactions (which may include changes in blood pressure and heart rate, low blood oxygen level, fever, shortness of breath, wheezing, swelling (eg, lips, around eyes, under the skin), rash, nausea, sweating, or shivering).<sup>9</sup>

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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*  
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On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes coronavirus disease 2019 (COVID-19).<sup>1</sup> On the basis of such determination, the Secretary of HHS on March 27, 2020, declared that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3), subject to terms of any authorization issued under that section.<sup>2</sup>

On February 9, 2021, the Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for emergency use of bamlanivimab and etesevimab administered together for the treatment of mild to moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progressing to severe COVID-19 and/or hospitalization. Bamlanivimab and etesevimab are neutralizing IgG1 monoclonal antibodies that bind to distinct but overlapping epitopes within the receptor binding domain of the spike protein of SARS-CoV-2. They are both investigational drugs and are not currently approved for any indication.

<sup>1</sup> U.S. Department of Health and Human Services, Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3. February 4, 2020.

<sup>2</sup> U.S. Department of Health and Human Services, Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3, 85 FR 18250 (April 1, 2020).

## Page 2 – Eli Lilly and Company

On February 25, 2021, FDA reissued the February 9, 2021 letter.<sup>3</sup> On August 27, 2021, FDA reissued the February 25, 2021 letter.<sup>4</sup>

On September 16, 2021, again having concluded that revising this EUA is appropriate to protect the public health or safety under section 564(g)(2) of the Act, FDA is reissuing the August 27, 2021 letter in its entirety, to also authorize bamlanivimab and etesevimab administered together for emergency use as post-exposure prophylaxis in certain adults and pediatric individuals.

Based on the review of the data from the Phase 2/3 BLAZE-1 trial (NCT04427501), a randomized, double-blind, placebo-controlled clinical trial, and the Phase 2 BLAZE-4 trial (NCT04634409), a randomized, double-blind, placebo-controlled clinical trial, it is reasonable to believe that bamlanivimab and etesevimab administered together may be effective for the treatment of mild to moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death, and that, when used under the conditions described in this authorization, the known and potential benefits of bamlanivimab and etesevimab administered together outweigh the known and potential risks of such products.

Additionally, based on the review of the topline analysis of data from BLAZE-2 Part 1 (also known as Trial J2X-MC-PYAD; NCT04497987), a Phase 3 randomized, double-blind, placebocontrolled trial evaluating bamlanivimab alone for prevention of COVID-19 in residents and staff of skilled nursing facilities following a confirmed reported case of SARS-CoV-2 infection at the facility, it is reasonable to believe that bamlanivimab and etesevimab administered together may be effective for use as post-exposure prophylaxis of COVID-19 in individuals who

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are at high risk for progression to severe COVID-19, including hospitalization or death, as described in the Scope of Authorization (Section II), and that, when used under such conditions, the known and potential benefits of bamlanivimab and etesevimab outweigh the known and potential risks of such product.

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of bamlanivimab and etesevimab administered together for treatment and as post-exposure prophylaxis of COVID-19, as described in the Scope of Authorization section of this letter (Section II) and subject to the terms of this authorization.

<sup>3</sup> FDA revised the condition on instructional and educational materials. New conditions were also incorporated on the establishment of a process for monitoring genomic databases for the emergence of global viral variants of SARS-CoV-2 and the assessment, if requested by FDA, of the activity of the authorized bamlanivimab and etesevimab against any global SARS-CoV-2 variant(s) of interest.

<sup>4</sup> FDA revised the authorized use for bamlanivimab and etesevimab administered together clarifying the meaning of “severe COVID-19” and further limited the use of bamlanivimab and etesevimab by authorizing bamlanivimab and etesevimab administered together only in those states, territories, and US jurisdictions in which the combined frequency of variants resistant to bamlanivimab and etesevimab administered together is less than or equal to 5%. Revisions were also incorporated to the conditions on compliance with cGMPs, product quality reporting, requests for CMC (chemistry, manufacturing and controls) changes to this authorization, the provision of samples of the authorized bamlanivimab and etesevimab to HHS, upon request, and the conditions on advertising and promotion.

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The randomized, double-blind, placebo-controlled trial – the gold standard for scientific research -- evaluated the efficacy and safety of a 3-day course of remdesivir given through an IV in 562 non-hospitalized patients at high risk for severe COVID.

Remdesivir demonstrated an 87% reduction in risk for COVID-19-related hospitalization or death compared with the placebo group.

"These latest data show remdesivir's potential to help high-risk patients recover before they get sicker and stay out of the hospital altogether," cardiologist Robert L. Gottlieb, of Baylor University Medical Center in Houston, said in the press release. Gottlieb was the lead investigator for the study.

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**Prevention:** Active Immunization: Vaccines

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- 986) 2021-10-07 Harper M: Eli Lilly says it's monoclonal antibody cocktail is effective treating Covid-19. STAT. <https://www.statnews.com/2020/10/07/eli-lilly-monoclonal-antibody-cocktail-covid-19/#:~:text=Policy%20Cheat%20Sheet-.Eli%20Lilly%20says%20its%20monoclonal%20antibody,effective%20in%20treating%20Covid%2D19&text=Eli%20Lilly%20said%20Wednesday,the%20emergency%20room%20or%20hospital.>
- 987) 2021-10-07 LaFraniere S, Weiland N: Pfizer asks F.D.A. to authorize its Covid-19 vaccine for children 5 to 11. The New York Times. <https://www.nytimes.com/2021/10/07/us/politics/pfizer-fda-authorization-children-5-11.html>
- 988) 2021-10-08 Mercedes C: VERIFY: Claim that the federal government is rationing monoclonal antibodies. KHOU 11 <https://www.khou.com/article/news/verify/verify-federal-government-is-rationing-monoclonal-antibodies/285-aae3608f-c439-4d4f-83de-4e6c76365081>
- 989) 2021-10-09 Jung S, McDowell RH: Abandonment. NCBI, StatPearls Publishing. <https://www.ncbi.nlm.nih.gov/books/NBK563285/>
- 990) 2020-2021 CDC, Centers for Disease Control and Prevention, National Center for Health Statistics: Provisional Death Counts for Coronavirus Disease 2019 (COVID-19), List of Topics: 1. Sex and Age. [https://web.archive.org/web/20210217175653/https://www.cdc.gov/nchs/nvss/vsrr/covid\\_weekly/index.htm#SexAndAge](https://web.archive.org/web/20210217175653/https://www.cdc.gov/nchs/nvss/vsrr/covid_weekly/index.htm#SexAndAge)
- 991) 2021-10-11 Katella K: 9 Things you need to know about the new COVID-19 pill. <https://www.yalemedicine.org/news/9-things-to-know-about-covid-pill>. Merck has applied to the Food and Drug Administration (FDA) for emergency use authorization (EUA) of the pill, called molnupiravir.
- 992) 2021-10-13 Jetelina K: Mixing vaccines: The study we've all been waiting for. <https://yourlocalepidemiologist.substack.com/p/mixing-vaccines-the-study-weve-all>
- 993) 2021-10-14. Scannell K: Trump ordered to give deposition in 2015 case involving alleged assault during Trump Tower demonstration. CNN politics. <https://www.cnn.com/2021/10/14/politics/trump-deposition-demonstration-new-york/index.html>

- 994) 2021-10-18: O'Donnell N: The passing of General Colin Powell. CBS Evening News, October 18, 2021. <https://www.cbsnews.com/video/101821-cbs-evening-news/#x>
- 995) 2021-10-19. Jetelina K: Why didn't Powell's vaccine work? <https://yourlocalepidemiologist.substack.com/p/why-didnt-powells-vaccine-work>
- 996) 2021-10-22 Wu KJ: No one will stop you from getting whatever booster you want. *The Atlantic*. <https://www.theatlantic.com/health/archive/2021/10/cdc-booster-choice-mix-and-match/620461/>
- 997) 2021-10-22 HHS.gov: Rear Admiral Denise Hinton – Deputy U.S. Surgeon General. <https://www.hhs.gov/about/leadership/denise-hinton.html>
- 998) 2021-10-25 Fauci A: NL01.Martin Memorial Lecture: COVID-19: Lessons learned and remaining challenges. ACS Clinical Congress October 23-27, 2021 | Virtual, October 25, 2021 8:30 CDT. <https://cattendee.abstractsonline.com/meeting/10371/Session/65> Dr. Anthony S. Fauci to discuss lingering COVID-19 challenges <https://www.acscnews.org/dr-anthony-s-fauci-to-discuss-lingering-covid-19-challenges/> <https://cattendee.abstractsonline.com/meeting/10371/Session/65>
- 999) 2021-10-25. Fauci AS: Martin Memorial Lecture (NL01 8:30 – 9:00 am Central Time). ACS Clinical Congress held virtually. Monday, October 25, 2021. <https://www.facs.org/publications/bulletin-brief/100521/clinicalcongress>
- 1000) 2021-10-26 Neel J: FDA advisory panel recommends Pfizer vaccine for kids ages 5 to 11. Shots Health News from NPR. <https://www.npr.org/sections/health-shots/2021/10/26/1049372524/fda-panel-recommends-pfizer-vaccine-for-kids-ages-5-to-11>
- 1001) 2021-10-27 Tin A: Some immunocompromised Americans can get four doses of COVID-19 vaccine. CBS News. <https://www.cbsnews.com/news/covid-19-vaccine-fourth-dose-booster-immunocompromised/>
- 1002) 2021-10-29 FDA: FDA authorizes Pfizer-BioNTech COVID-19 vaccine for emergency use in children 5 to 11 years of age. <https://www.fda.gov/news-events/press-announcements/fda-authorizes-pfizer-biontech-covid-19-vaccine-emergency-use-children-5-through-11-years-age>
- 1003) 2021-10-29 McGinley L, Shepherd K: FDA authorizes Pfizer-BioNTech vaccine for children 5 to 11. The Washington Post <https://www.washingtonpost.com/health/2021/10/29/fda-approves-vaccine-for-kids/>
- 1004) 2021-10-29 Gazis O: Intelligence agencies unlikely to find origins of COVID-19 without cooperation from China. CBS News, October 29, 2021 <https://www.cbsnews.com/news/covid-19-origins-intelligence-community-china/>

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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*  
**Prevention:** *Active Immunization:* Vaccines

**1005)** 2021-10-29 Vazquez M, Liptak K: God love ya: Warm relationship between the world's most powerful Catholics on display as Biden and Pope Francis meet. CNN politics.  
<https://www.cnn.com/2021/10/29/politics/pope-francis-joe-biden-meeting/index.html>

**1006)** 2021-11-02 Aripaka P, Burger L: Lilly pulls COVID-19 treatment from EU review while U.S. stocks up. REUTERS Healthcare & Pharmaceuticals  
<https://www.reuters.com/business/healthcare-pharmaceuticals/lilly-withdraws-eu-rolling-review-covid-19-antibodies-2021-11-02/>

**1007)** 2021-11-04 Chappell B: The U.K. approves Merck's COVID-19 antiviral pill, calling it a world first. NPR Coronavirus Updates. <https://www.npr.org/sections/coronavirus-live-updates/2021/11/04/1052281073/uk-merck-molnupiravir-covid-drug>

**1008)** 2021-11-05: Pfizer: Pfizer's novel COVID-19 oral antiviral treatment candidate reduced risk of hospitalization or death by 89% in Interim Analysis of Phase 2/3 EPIC-HR study.  
<https://www.pfizer.com/news/press-release/press-release-detail/pfizers-novel-covid-19-oral-antiviral-treatment-candidate>

**1009)** 2021-11-05 Chappell B: Pfizer says its COVID-19 pill cuts disease's worst risks by 89%. NPR, Coronavirus Updates. <https://www.npr.org/sections/coronavirus-live-updates/2021/11/05/1052679112/pfizer-covid-pill-treatment#:~:text=Pfizer%20says%20that%20its%20COVID,oral%20medicine%20is%20called%20Paxlovid.>

The oral medicine is called Paxlovid. Similar to Merck's new pill that was approved in the U.K. on Thursday, Pfizer said its drug showed good results when administered within five days of the first COVID-19 symptoms.

**1010)** 2021-11-08 Mayo Clinic | Business Development. Impact Story: Cologuard. Cancer screening revolution. FDA-approved noninvasive colorectal screening.  
<https://businessdevelopment.mayoclinic.org/portfolio/cancer-screening-revolution/>

**1011)** 2021-11-08 Regeneron: New phase 3 analyses show that a single dose of REGEN-COV (Casirivimab and Imdevimab) provides long-term protection against COVID-19.  
<https://newsroom.regeneron.com/news-releases/news-release-details/new-phase-3-analyses-show-single-dose-regen-covr-casirivimab-and>

Compared to placebo (n=842), people who received a single dose of REGEN-COV (n=841) experienced:

- 81.6% reduced risk of developing COVID-19 during the pre-specified follow-up period, between months 2-8 (7 REGEN-COV, 38 placebo; 95% confidence interval [CI]: 59.8%, 91.6%; nominal p<0.0001).

- 81.5% reduced risk of developing COVID-19 at any time during the 8 months after receiving REGEN-COV (20 REGEN-COV, 108 placebo; 95% CI: 70.6%,88.4%; nominal  $p < 0.0001$ ).
- During the 8-month assessment period, 0 individuals in the REGEN-COV group were hospitalized due to COVID-19, compared to 6 individuals in the placebo group (1 person in the first month; 5 people during months 2-8). There were no deaths due to COVID-19 in any treatment group during the 8-month assessment period, and there were no new safety signals identified for REGEN-COV.

**1012)** 2021-11-08 Roche Investor Relations, Dr. Karl Mahler and Jon Kaspar Bayard: Investor Update: New Phase 3 analyses show that a single dose of REGEN-COV (casirivimab and imdevimab) provides long-term protection against COVID-19.

<https://www.roche.com/investors/updates/inv-update-2021-11-08.htm>

**1013)** 2021-11-09 FDA: Template for developers of molecular and antigen diagnostic COVID-19 tests for home use. [Molecular and Antigen Home Use Test Template – US Food ... and Supplemental template for Molecular and Antigen Diagnostic ... that are downloadable at <https://www.google.com/search?q=Template+for+developers+of+molecular+and+antigen+diagnostic+COVID-19+tests+for+home+use&oq=Template+for+developers+of+molecular+and+antigen+diagnostic+COVID-19+tests+for+home+use&aqs=chrome..69i57j0j15&sourceid=chrome&ie=UTF-8> ].

**1014)** 2021-11-11 Armitage H: COVID-19 nasal spray vaccine in the works at Stanford Medicine. <https://med.stanford.edu/news/all-news/2021/11/effort-to-develop-covid-vaccine-nasal-spray.html>

**1015)** 2021-11-12 Diamond D: Messonnier, Birx detail political interference in last year's coronavirus response. The Washington Post. <https://www.washingtonpost.com/health/2021/11/12/messonnier-birx-coronavirus-response-interference/>

**1016)** 2021-11-16 Linton C, Navarro A: Wyoming GOP votes to no longer recognize Liz Cheney. <https://www.cbsnews.com/news/liz-cheney-wyoming-republican-party-recognize/>  
In this news report, it mentions that Kayleigh McEnany was given a subpoena to testify by the House select committee investigating the January 6 attack on the Capitol.

**1017)** 2021-11-17 Tin A: Pfizer asks FDA to grant emergency authorization for its COVID-19 pill. CBS News November 17, 2021. <https://www.cbsnews.com/news/covid-pill-pfizer-seeks-fda-authorization/>

**1018)** 2021-11-17 O'Keefe E, Brown K: U.S. bishops approve Communion guidelines after debate on Biden's eligibility. CBS NEWS. <https://www.cbsnews.com/news/catholic-bishops-vote-biden-pelosi-communion-abortion-rights/>

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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*  
**Prevention:** *Active Immunization:* Vaccines



- 1019)** 2021-11-17 O'Shaughnessy JA: Regeneron Pharmaceuticals, Inc. EUA 091 regarding REGEN-COV. <https://www.fda.gov/media/145610/download>
- 1020)** 2021-11-18 Picchi A: OSHA is suspending enforcement of the government's new employer vaccine rule. CBS News <https://www.cbsnews.com/news/covid-vaccine-mandate-osha-suspending-enforcement/>
- 1021)** 2021-11-18 Gupta A, Gonzalez-Rojas Y, Juarez E, Casal MC, Moya J, Falci DR, Sarkis E, Solis J, Zheng H, Scott N, Cathcart AL, Hebner CM, Sager J, Mogailian E, Tipple C, Peppercorn A, Alexander E, Pag PS, Free A, Brinson C, Aldinger M, Shapiro AE, for the COMET-ICE Investigators: Early treatment for Covid-19 with SARS-Cov-2 neutralizing antibody Sotrovimab. N Engl J Med 2021 Nov 18; 385 (21): 1941-1950. <https://www.nejm.org/doi/pdf/10.1056/NEJMoa2107934?articleTools=true>
- 1022)** 2021-11-18 Korley FK, Durkalski-Mauldin V, Yeatts SD, Davenport RD, Dumont LJ, El Kassir N, Foster LD, Hah JM, Jaiswall S, Kaplan A, Lowell E, Mcdyer JF, Quinn J, Triulzi DJ, Van Huysen C, Stevenson VLM, Yadav K, Jones CW, Kea B, Burnett A, Reynolds JC, Greineder CF, Haas NL, Beiser DG, Silbergleit R, Barsa W, Callaway CW, for the SIREN-C3PO Investigators: Early convalescent plasma for high-risk outpatients with Covid-19. N Engl J Med 2021 Nov 18; 385 (21): 1951-1960. [SIREN-C3PO ClinicalTrials.gov number, NCT04355767.] <https://www.nejm.org/doi/pdf/10.1056/NEJMoa2103784?articleTools=true>

The Food and Drug Administration (FDA) approved an Investigational New Drug application for the trial. A central institutional review board (Advarra) reviewed and approved the trial protocol for all participating sites. (Advarra is a propriety company which on their internet listing are: Industry Experts—The Advarra Advantage: Our Expertise:

The Advarra advantage is built on our industry and domain expertise. Our experts are change agents and thought leaders with deep experience in clinical research. Together, we solve mission-critical challenges and bring life-changing therapies to participants faster. (Please note, Advarra's experts listed on their website <https://www.advarra.com/about/industry-experts/> include **NO MEDICAL CLINICIANS LIKE AN M.D. OR A D.O.** In short, the SIREN-C3PO clinical trial NCT04355767 was reviewed by a proprietary company and **NOT** by any University School of Medicine IRB, any participating Hospital IRB, or the FDA's IRB directly.)

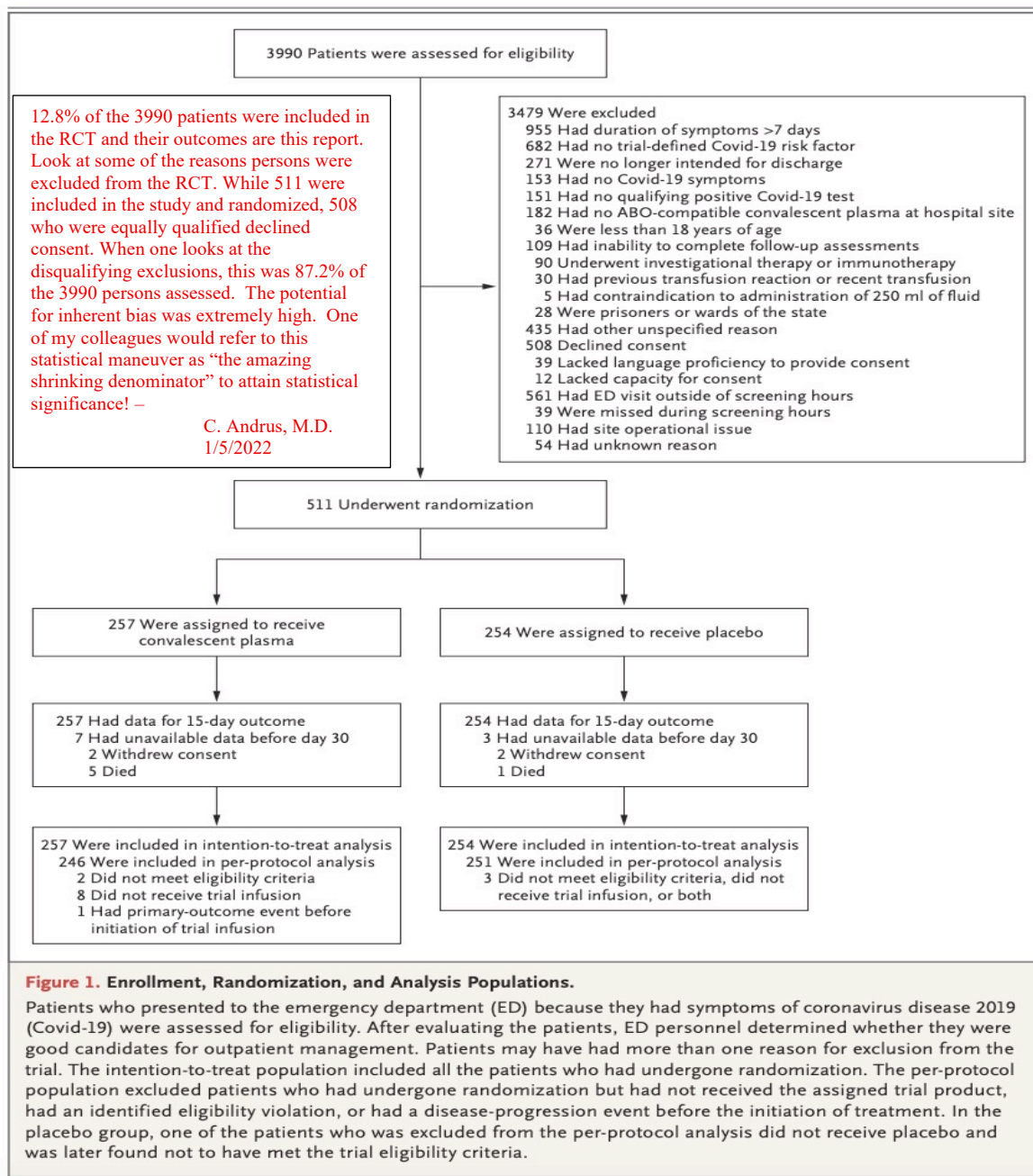
PLEASE note that the complete article and the supplementary appendix can be found:

Korley FK, Durkalski-Maudin V, Yeatts SD, Schulman K, Davenport RD, Dumont LJ, El Kassir N, Foster LD, Hah JM, Jaiswal S, Kaplan A, Lowell E, et al., for the DIREN-C3PO Investigators\*: Early convalescent plasma for high-risk outpatients with Covid-19. URL from article N Engl J Med 2021 Nov 18; 385: 1951-1960. <https://www.nejm.org/doi/10.1056/NEJMoa2103784> This reference from the article is just an abbreviation; The full article is <https://www.nejm.org/doi/pdf/10.1056/NEJMoa2103784?articleTools=true> and the

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Supplementary Appendix which is very important can be found at  
([https://www.nejm.org/doi/suppl/10.1056/NEJMoa2103784/suppl\\_file/nejmoa2103784\\_appendix.pdf](https://www.nejm.org/doi/suppl/10.1056/NEJMoa2103784/suppl_file/nejmoa2103784_appendix.pdf)).



In Figure 1. **Enrollment, Randomization, and Analysis Populations**, of the 3990 patients presenting to the Emergency Room, 3479 (87.2%) were excluded as listed in the box above. The number of eligible patients that refused to participate

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in this placebo RCT was 508 and with the 561 that presented outside of ED screening hours and thus were rejected. These two exclusion factors totaled over twice as many patients (1069) as were included in this study of 511. What is more, when the NIH announced the closure of this trial on March 2, 2021 never reaching its statistical-directed goal of 900 patients (minimum  $\beta$  that the researchers agreed upon for a valid study), it proceeded to conclude that early administration of Passive Immunization via COVID-19 Convalescent Plasma (CCP) was not helpful. By excluding so many individuals, this study is probably a skewed, underpowered trial which the NIH and the editors of *The New England Journal of Medicine* should never have published.

It should also be noted that at the end of the author list on the front page of this article, it is stated: ...for the SIREN-C3PO Investigators\* where the “\*” refers to the statement in the right margin:

\*A list of the SIREN-C3PO investigators is provided in the Supplementary Appendix, available at NEJM.org which is 20 pages long ([https://www.nejm.org/doi/suppl/10.1056/NEJMoa2103784/suppl\\_file/nejmoa2103784\\_appendix.pdf](https://www.nejm.org/doi/suppl/10.1056/NEJMoa2103784/suppl_file/nejmoa2103784_appendix.pdf)) In this Supplementary Appendix major criteria for inclusion in the study changed from Protocol Version 1 of June 17, 2020 through Version 2 of July 2, 2020, Version 3 of September 7, 2020, Version 4 of November 3, 2020 to Version 5, February 16, 2021:

Has at least one study defined risk factor for severe COVID-19 illness:

Age  $\geq$  50 years; hypertension; diabetes; coronary artery disease; chronic lung disease; chronic kidney disease; immunosuppression

Yet, in Table 1. **Characteristics of the Patients at Baseline:**

Characteristic	Convalescent Plasma (N=257)	Placebo (N=254)
Median age (IQR)	54 (42-62)	54 (40-62)

there were patients of 42-49 years in the Convalescent Plasma group and patients of 40-49 years in the placebo group. Those patients should have been excluded due to their “younghness” that violated the stated inclusion criteria of all five Protocol versions of this trial. Were the SIREN-C3PO investigators, the NIH, and the editors of *The New England Journal of Medicine* being truthful to the American public? Has this paper done a disservice to the American public and to the World? As the NEJM attests to the participation in the *International Committee of Medical Journal Editors (ICMJE)*, they owe the American people an independent (independent from the U.S. Government and *The New England Journal of Medicine*) peer review of this paper with regards to appropriateness: Simply put, can this paper even conclude that which it concludes?

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**Treatment:** Passive Immunization: COVID-19 Convalescent Plasma and Antibodies and Antivirals  
**Prevention:** Active Immunization: Vaccines

- 1023)** 2021-11-18 CBS Interactive Inc.: Frozen vials marked “Smallpox” found in lab freezer in Pennsylvania, CDC says. <https://www.cbsnews.com/news/smallpox-vials-lab-freezer-pennsylvania-cdc/>
- 1024)** 2021-11-18 Picchi A: OSHA is suspending enforcement of the government’s new employer vaccine rule. <https://www.cbsnews.com/news/covid-vaccine-mandate-osh-suspending-enforcement/>
- 1025)** 2021-11-18 Kimball S: Biden administration buys \$10 million courses of Pfizer Covid treatment pill in \$5 billion deal. <https://www.cnn.com/2021/11/18/biden-administration-buys-10-million-courses-of-pfizer-covid-treatment-pill.html>
- 1026)** 2021-11-19 Collin L: Upper Midwest faces spike in COVID-19 infections: “It’s unprecedented.” CBS Evening News, November 19, 2021. <https://www.cbsnews.com/news/covid-19-upper-midwest-minnesota-spike/>
- 1027)** 2021-11-19 CBS News: U.S. Scientist says he’s found the real COVID patient zero, and “strong evidence” pandemic started at animal market. CBS News, November 19, 2021. <https://www.cbsnews.com/news/origin-covid-19-us-scientist-patient-zero-wuhan-china-evidence-market/>
- 1028)** 2021-11-19 FDA: FDA NEWS RELEASE: Coronavirus (COVID-19) Update: FDA expands eligibility for COVID-19 Vaccine boosters. November 19, 2021. <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-expands-eligibility-covid-19-vaccine-boosters>
- 1029)** 2021-11-19 Tin A: CDC authorizes COVID vaccine boosters for all adults. CBS News, November 19, 2021. <https://www.cbsnews.com/news/covid-vaccine-booster-shot-cdc-fda-authorization/>
- 1030)** 2021-11-21 The Tabernacle Choir at Temple Square: November 21, 2021 - #4810 Music & the Spoken Word. (This played on KMOX radio, St. Louis, MO at 6:00 a.m. while on my way to the St. Louis (John Cochran division) VAMC to round on the Veteran patients of General Surgery II. Listening to this message epitomized that of which the concept of gratitude of Thanksgiving Day is engendered and our assurance by the Constitution and the Bill of Rights of our freedoms of which we all-to-often take for granted.) <https://www.thetabernaclechoir.org/videos/november-21-2021-4810-music-and-the-spoken-word.html>
- 1031)** 2021-11-21 Fauci A: Fauci says he’d be “astounded” if there wasn’t an autopsy on what went wrong in COVID response, CBS News. (Attempt of accessing this website on Google: Fauci Brennan *Face the Nation* on November 22, 2021 was unsuccessful but “autopsy”

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provided by yahoo): <https://www.yahoo.com/now/fauci-says-hed-astounded-wasnt-150638991.html>

Margaret Brennan: Why aren't we having a national conversation about what went wrong? I mean, apart from this room right now, why isn't there a 9/11-type commission?

Anthony Fauci, M.D.: Yeah. I think what's going to happen is that you are going to see that for sure, Margaret. I think the lack of doing that now is because you're focusing on getting this thing under control. I would be astounded if we didn't have a very serious look at what went right, what went wrong, from a public health standpoint, from a local standpoint, from a global standpoint. I don't think that the public should imagine that this is going to go through—with already 760,000 Americans dying, and 40 plus million, at least, being infected. Close to 6 million people globally dying—and we're not going to look back at this and tear it apart, examine it, **do an autopsy on it** and try and figure out [AUDIO OUT]..

WHEN the Wayback Machine (Internet Archive) was accessed November 22, 2021 of the only capture for the Yahoo version of Face the Nation of Nov 21, 2021:

<https://web.archive.org/web/20211121161530/https://www.yahoo.com/now/fauci-says-hed-astounded-wasnt-150638991.html> yielded:

yahoo!

**CBS News: Fauci says he'd be "astounded" if there wasn't an autopsy on what went wrong in COVID response" Sun, November 21, 2021, 4:06 PM –Dr. Anthony Fauci tells Margaret Brennan in a wide-ranging conversation that he expects a full investigation into what went wrong in the Coronavirus response.**

BUT THE ACTUAL INTERVIEW CANNOT BE OPENED stating: Cannot Play Video—Due to license restrictions; this video can only be viewed on Yahoo. RS-100-204.

WHEN on November 23, 2021, the Google attempt at searching: "Fauci Brennan Face the Nation" failed, searching for "Fauci Brennan Sixty Minutes" yielded the official CBS News website:

<https://www.cbsnews.com/video/fauci-says-hed-be-astounded-if-there-wasnt-an-autopsy-on-what-went-wrong-in-covid-response/#x>

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Margaret Brennan: It's been almost two years since a mysterious virus began circulating in Wuhan, China. And there are still far more questions than answers about where it came from and how we can prepare for the next pandemic. For our broadcast Sunday we talked with Dr. Anthony Fauci to get his thoughts on just some of those questions. Here's a preview:

Margaret Brennan: Why aren't we having a national conversation about what went wrong? I mean, apart from this room right now, why isn't there a 9/11-type commission?

Anthony Fauci, M.D.: Yeah. I think what's going to happen is that you are going to see that for sure, Margaret. I think the lack of doing that now is because you're focusing on getting this thing under control. I would be astounded if we didn't have a very serious look at what went right, what went wrong, from a public health standpoint, from a local standpoint, from a global standpoint. **I don't think that the public should imagine that this is going to go through—with already 760,000 Americans dying, and 40 plus million, at least, being infected. Close to 6 million people globally dying—and we're not going to look back at this and tear it apart, examine it, do an autopsy on it and try and figure out.**

Margaret Brennan: Dr. Anthony Fauci coming up Sunday on Face the Nation.

When the web.archive using the official CBS New URL site above, Margaret Brennan video appears speaking without sound and when the arrow is the screen becomes black with a white circle spiraling in the center. The caption underneath reads: Fauci says he'd be "astounded" if there wasn't an autopsy on what went wrong in COVID response. Dr. Anthony Fauci tells Margaret Brennan in a wide-ranging conversation that he expects a full investigation into what went wrong in the Coronavirus response.

<https://web.archive.org/web/20211121152005/https://www.cbsnews.com/video/fauci-says-hed-be-astounded-if-there-wasnt-an-autopsy-on-what-went-wrong-in-covid-response/>

**1032)** 2021-11-19 KFF-Henry J Kaiser Family Foundation: Status of State Medicaid Expansion Decisions: Interactive Map. <https://www.kff.org/medicaid/issue-brief/status-of-state-medicaid-expansion-decisions-interactive-map/>

**1033)** 2021-11-19, last updated: Boston National Historical Park: Smallpox, Inoculation, and the Revolutionary War. <https://www.nps.gov/articles/000/smallpox-inoculation-revolutionary-war.htm>

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1034) 2021-11-23 Trump D, Jr: @DonaldJTrumpJr

<https://twitter.com/DonaldJTrumpJr/status/1463366937065390085/photo/1>

<https://web.archive.org/web/20211124215038/https://twitter.com/DonaldJTrumpJr/status/1463366937065390085/photo/1>

1035) 2021-11-23 CBS News: Full transcript of “Face the Nation” on November 21, 2021. “On this “Face the Nation” broadcast moderated by Margaret Brenna:” **The transcript has yet to be released but nowhere in the titles is Dr. Anthony Fauci listed.**

Sen. Kirsten Gillibrand, (D-NY)

Sen. Ted Cruz, (R-TX)

Derrick Johnson, President and CEO, NAACP

Dr. Scott Gottlieb, Former FDA Commissioner

Anthony Salvanto, CBS News Elections & Surveys Director

<https://web.archive.org/web/20211121192431/https://www.cbsnews.com/news/full-transcript-of-face-the-nation-on-november-21-2021/>

<https://www.cbsnews.com/news/full-transcript-of-face-the-nation-on-november-21-2021/>

1036) 2021-11-28 Fauci A, Brennan M: Transcript: Dr. Anthony Fauci on “Face the Nation,” November 28, 2021. CBS NEWS, Face the Nation, 2021 November 28, 2021, 7:21 AM  
<https://www.cbsnews.com/news/transcript-dr-anthony-fauci-on-face-the-nation-november-28-2021/>

***Please note that the statement regarding autopsy was edited out from the discussion that aired on Sunday morning Face the Nation on November 28, 2021 on the St. Louis affiliate KMOV:***

DR. FAUCI: Yeah, I think what's going to happen is that you are going to see that for sure, MARGARET. I think the lack of doing that now is because you're focusing on getting this thing under control. I would be astounded if we didn't have a very serious look at what went right, what went wrong, from a public health standpoint, from a local standpoint, from a global standpoint. I don't think that the public should imagine that this is going to go through with already 760,000 Americans dying and 40 plus million at least being infected, close to six million people globally dying. **And we're not going to look back at this and tear it apart, examine it, do an autopsy on it and try and figure out.** So people should not think that that's not going to happen. It's not happening now because everybody's focusing on getting this thing under control.

1037) 2021-11-28 Bice A: Fauci: ‘I’m going to be saving lives and they’re going to be lying.’ POLITICO <https://www.politico.com/news/2021/11/28/fauci-lying-covid-research-cruz-523412>

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- 1038)** 2021-11-29 Kimball S: Pfizer CEO confident Covid treatment pill will be effective against omicron variant. <https://www.cnn.com/2021/11/29/pfizer-ceo-confident-covid-treatment-pill-effective-against-omicron-variant.html>
- 1039)** 2021-12 Personalis, Inc.: Veterans Health Administration 75 Years: *A legacy of service. The future of care.* Personalis, Inc., 1330 O'Brien Drive, Menlo Park, CA. 94025. [www.personalis.com](http://www.personalis.com) wrightusa.com, page 20.
- 1040)** 2021-12-01 Lederer EM: Fauci says COVID diverted resources from fighting AIDS. <https://www.aol.com/news/fauci-says-covid-diverted-resources-035825200-153355420.html>
- 1041)** 2021-12-02. Weinreich DM and Others: e81 REGEN-COV Antibody Combination and Outcomes in Outpatients with Covid-19. D.M. Weinreich and Others.

2021-09-29 Weinreich DM, Sivapalasingam S, Norton T, Ali S, Gao H, Bhore R, Xiao J, Hooper AT, Hamilton JD, Musser BJ, Rofail D, Hussein M, Im J, Atmodjo DY, Perry C, Pan C, Mahmood A, Hosain R, Davis JD, Turner KC, Baum A, Kyratsous CA, Kim Y, Kampman W, Roque-Guerrero L, Acloque G, Aazami H, Cannon K, Simon-Campos, Bocchini JA, Kowal B, DiCioccio AT, Soo Y, Geba GP, Stahl N, Lipsich L, Braunstein N, Herman G, Yancopoulos GD, for the Trial Investigators\*: REGEN-COV antibody combination and outcomes in outpatients with Covid-19. N Engl J Med posted on NEJM.org on September 29, 2021. <https://www.nejm.org/doi/pdf/10.1056/NEJMoa2108163?articleTools=true> with the "\*" which is the complete article: <https://www.nejm.org/doi/full/10.1056/NEJMoa2108163> of September 29, 2021.

On the hardcopy version of this paper is noted in the front page index of *The New England Journal of Medicine*, 2021 December 2; 385 (23), front page INDEX:

**e81** REGEN-COV Antibody Combination and Outcomes in Outpatients with Covid-19. D.M. Weinreich and Others but the article is not in this hardcopy but in the electronic format only: <https://www.nejm.org/doi/full/10.1056/NEJMoa2108163> and for the entire supplement: [https://www.nejm.org/doi/suppl/10.1056/NEJMoa2108163/suppl\\_file/nejmoa2108163\\_appendix.pdf](https://www.nejm.org/doi/suppl/10.1056/NEJMoa2108163/suppl_file/nejmoa2108163_appendix.pdf)

- 1042)** 2021-12-02 Witberg G, Barda N, Hoss S, Richter I, Wiessman M, Aviv Y, Grinberg T, Auster O, Dagan N, Balicer RD, Kornowski R: Myocarditis after Covid-19 vaccination in a large health care organization. N Engl J Med 2021 December 2; 385 (23): 2132-2139. <https://www.nejm.org/doi/pdf/10.1056/NEJMoa2110737?articleTools=true>

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<https://www.nejm.org/doi/full/10.1056/NEJMoa2110737> which is the electronic version published on October 6, 2021.

- 1043)** 2021-12-02 Mevorach D, Anis E, Cedar N, Bromberg M, Nadir E, Olsha-Castell S, Arad D, Hasin T, Levi N, Amir O, Meir K, Cohen D, Dichtiar R, Novick D, Hershkovitz Y, Dagan R, Leitersdorf I, Ben-Ami R, Miskin I, Saliba W, Muhsen K, Levi Y, Green MS, Keinan-Boker L, Alroy-Preis S: Myocarditis after BNT162b2 mRNA Vaccine against Covid-19 in Isreal. N Engl J Med 2021 December 2; 385 (23): 2140-2149.  
<https://www.nejm.org/doi/pdf/10.1056/NEJMoa2109730>
- 1044)** 2021-12-02 Caforio ALP: Receipt of mRNA Vaccine against Covid-19 and myocarditis. N Engl J Med 2021 December 2; 385 (23): 2189-2190.  
<https://www.nejm.org/doi/pdf/10.1056/NEJMe2116493?articleTools=true>
- 1045)** 2021-12-02 Chutel L, Pénza-Peña R: Prior infection is little defense against virus variant, scientists say. Evidence from South Africa, where the Omicron variant already dominates, shows a high rate of reinfection of people who have already had the coronavirus. The New York Times <https://www.nytimes.com/2021/12/02/world/africa/virus-omicron-variant-reinfection.html>
- 1046)** 2021-12-03 Albert V, Tin A: Omicron COVID-19 variant detected in 5 states, a day after first case was reported in U.S. CBS News <https://www.cbsnews.com/news/omicron-variant-covid-19-cases-detected-united-states/>
- 1047)** 2021-12-03 FDA: FDA expands authorization of two monoclonal antibodies for treatment and post-exposure prevention of COVID-19 to younger pediatric patients, including newborns. U.S. Food and Drug Administration News Release.  
<https://www.fda.gov/news-events/press-announcements/fda-expands-authorization-two-monoclonal-antibodies-treatment-and-post-exposure-prevention-covid-19>

#### PLEASE NOTE:

**Mr. President**, the actual EUA regarding this FDA News Release was based on the EUA letter by RADM Denise M. Hinton, R.N., M.S., F.D.A. Chief Scientist, on September 16, 2021. Mr. President, over the last 18 months, RADM Hinton has issued FDA EUAs regarding *Passive Immunization agents* like COVID-19 Convalescent Plasma; Monoclonal Antibodies and Antibody Cocktails, etc.—because that is her job. She has walked the straight and narrow in responsibly issuing these EUAs for the last 18 months for that is her job; and she has done it admirably! In those introductory discussions of each of the EUAs she has laid out the evolutionary histories of these drugs and biologic agents and the justifications and directions on how to clinically administer them. Unfortunately, every EUA continues the status of the drug or biologic as *Investigational (Experimental)*. What does that mean? – It means that clinically a physician has to apply for an

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individual FDA *Investigational New Drug (IND)* application every time he/she has a patient who has contracted COVID-19 and administration of the drug or biologic is indicated.

The FDA tried to circumvent the need for individual physicians requesting individual INDs for individual patients regarding COVID-19 Convalescent Plasma from March 24, 2020 until August 23, 2020 by issuing an Expanded Access authorization. An expanded access authorization is by FDA/NIH definition “compassionate” use – providing an *Investigational Drug* given off protocol with the stipulation that any outcome data cannot be used to generate any prospective research information.

**1048)** 2021-12-03 Lilly: Lilly’s bamlanivimab with etesevimab authorized as the first and only neutralizing antibody for emergency use in COVID-19 patients under the age of 12.  
<https://investor.lilly.com/node/46306/pdf>

**1049)** 2021-12-03 Enago Academy: Quick guide to biostatistics in clinical research: Hypothesis testing. <https://www.enago.com/academy/quick-guide-to-biostatistics-in-clinical-research-hypothesis-testing/>

2021-01-22 Enago Academy: A quick guide to clinical trials (Part 1: An Overview).  
<https://www.enago.com/academy/a-quick-guide-to-clinical-trials-part-1-an-overview/>

2018-05-23 Enago Academy: A quick guide to clinical trials (Part 2: The Process).  
<https://www.enago.com/academy/a-quick-guide-to-clinical-trials-part-2-the-process/>

**1050)** 2021-12-06 wcg FDANEWS: FDA updates EUA for Eli Lilly’s COVID-19 antibody cocktail to include young children. <https://www.fdanews.com/articles/205656-fda-updates-eua-for-eli-lillys-covid-19-antibody-cocktail-to-include-young-children>

**1051)** 2021-12-07 World Health Organization: WHO recommends against the use of convalescent plasma to treat COVID-19. December 7, 2021.  
<https://www.who.int/news/item/07-12-2021-who-recommends-against-the-use-of-convalescent-plasma-to-treat-covid-19#:~:text=Convalescent%20plasma%20is%20a%20transfusion,while%20it%20has%20significant%20costs>

**1052)** 2021-12-08 Kimball S: Pfizer will submit full data on Covid treatment pill to the FDA in a few days, CEO says. CNBC PRO Dec 8, 2021. <https://www.cnbc.com/2021/12/08/pfizer-will-submit-full-data-on-covid-treatment-pill-to-the-fda-in-a-few-days-ceo-says.html>

**1053)** 2021-12-08 FDA News Release: Coronavirus (COVID-19) Update: FDA authorizes new long-acting monoclonal antibodies for pre-exposure prevention of COVID-19 in certain individuals. <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19->


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[update-fda-authorizes-new-long-acting-monoclonal-antibodies-pre-exposure#:~:text=Today%2C%20the%20U.S.%20Food%20and,years%20of%20age%20and%20older](#) Per an e-mail of February 18, 2022, 1:31 PM from the Deputy Chief of Staff—John Cochran Division, VA St. Louis Health Care System: The St. Louis VA has received a very limited supply of Evusheld for initial distribution. The Scarce Resource Team has planned an allocation method to maximize the ethical principles of respect, consistency, stewardship, transparency, and equity.

- 1054)** 2021-12-08 Jimenez D: Covid-19: GSK's sotrovimab retains activity against Omicron variant. Pharmaceutical Technology. [https://www.pharmaceutical-technology.com/special-focus/covid-19/covid-19-gsk-sotrovimab-activity-omicron-variant/#:~:text=GlaxoSmithKline%20\(GSK\)%20and%20Vir%20Biotechnology,%2DCoV%2D2%20variant%20Omicron](https://www.pharmaceutical-technology.com/special-focus/covid-19/covid-19-gsk-sotrovimab-activity-omicron-variant/#:~:text=GlaxoSmithKline%20(GSK)%20and%20Vir%20Biotechnology,%2DCoV%2D2%20variant%20Omicron).
- 1055)** 2021-12-08 NIH / NIAID: COVID-19 single-dose nasal vaccine designed for infants, children. <https://www.niaid.nih.gov/news-events/covid-19-single-dose-nasal-vaccine>
- 1056)** 2021-12-13 Supreme Court of the U.S.: JOSEPH R. BIDEN, Jr, PRESIDENT OF THE UNITED STATES, et al., APPLICANTS 21A240 v. MISSOURI, et al. and XAVIER BECERRA, SECRETARY OF HEALTH AND HUMAN SERVICES, et al APPLICANTS 21A241 v. LOUISIANA, et al. on applications for stays. [https://www.supremecourt.gov/opinions/21pdf/21a240\\_d18e.pdf](https://www.supremecourt.gov/opinions/21pdf/21a240_d18e.pdf)
- 1057)** 2021-12-16 AstraZeneca: EVUSHELD long-acting antibody combination retains neutralizing activity antibody combination retains neutralizing activity against Omicron variant in independent FDA study. <https://www.astrazeneca-us.com/media/press-releases/2021/evusheld-long-acting-antibody-combination-retains-neutralizing-activity-against-omicron-variant-in-independent-fda-study.html>
- 1058)** 2021-12-16 NIH: COVID-19 Treatment Guidelines. <https://www.covid19treatmentguidelines.nih.gov/therapies/anti-sars-cov-2-antibody-products/anti-sars-cov-2-monoclonal-antibodies/>
- 1059)** 2021-12-16 NIH: Anti-SARS-CoV-2 Monoclonal Antibodies. <https://www.covid19treatmentguidelines.nih.gov/therapies/anti-sars-cov-2-antibody-products/anti-sars-cov-2-monoclonal-antibodies/>
- 1060)** 2021-12-16 NIH: Anti-SARS-CoV-2 Monoclonal Antibodies, Table A. (Last updated 16, 2021) <https://www.covid19treatmentguidelines.nih.gov/tables/table-a/> According to the Wayback Machine there are digital copies of updates going back to August 6, 2021 with the NIH "last update" is August 4, 2021. <https://web.archive.org/web/20210806205833/https://www.covid19treatmentguidelines.nih.gov/tables/table-a/>

<div>  <b>COVID-19 Treatment Guidelines</b> <div>Search</div> </div>									
<div> <a href="#">About the Guidelines</a> <a href="#">Overview</a> <a href="#">Management</a> <a href="#">Therapies</a> <a href="#">Special Populations</a> </div>									
<a href="#">Home</a> <a href="#">Therapies</a> <a href="#">Anti-SARS-CoV-2 Antibody Products</a> <a href="#">Anti-SARS-CoV-2 Monoclonal Antibodies</a> <a href="#">Anti-SARS-CoV-2 Monoclonal Antibodies</a>									
<h2>Anti-SARS-CoV-2 Monoclonal Antibodies</h2> <p>Last Updated: December 16, 2021</p>									
<div> <div>Eli Lilly</div> <div>Regeneron</div> <div>GlaxoSmithKline</div> </div>									
WHO Label	Pango Lineage	CDC Variant Class	Notable Mutations	BAM Plus ETE	CAS Plus IMD	SOT			
				In Vitro Susceptibility <sup>a</sup>	Anticipated clinical activity	In Vitro Susceptibility <sup>a</sup>	Anticipated clinical activity	In Vitro Susceptibility <sup>a</sup>	Anticipated clinical activity
Alpha	B.1.1.7	VBM	N501Y	No change	Active	No change	Active	No change	Active
Beta	B.1.351	VBM	K417N, E484K, N501Y	Marked reduction	Unlikely to be active	No change <sup>b</sup>	Active	No change	Active
Gamma	P.1	VBM	K417T, E484K, N501Y	Marked reduction	Unlikely to be active	No change <sup>b</sup>	Active	No change	Active
Delta	B.1.617.2, non-AY.1/AY.2	VOC	L452R, T478K	No change	Active	No change	Active	No change	Active
Omicron	B.1.1.529	VOC	K417N, N440K, G446S, E484A, Q493R, N501Y	Anticipated marked reduction	Unlikely to be active	Anticipated marked reduction	Unlikely to be active	Anticipated no change <sup>a4</sup>	Active

<sup>a</sup> Based on the fold reduction in susceptibility reported in the FDA EUAs.<sup>5,7</sup>

<sup>b</sup> Marked change for CAS and no change for IMD. The combination of CAS plus IMD appears to retain activity against the variant.

**Key:** BAM = bamlanivimab; CAS = casirivimab; CDC = Centers for Disease Control and Prevention; ETE = etesevimab; EUA = Emergency Use Authorization; FDA = Food and Drug Administration; IMD = imdevimab; SOT = sotrovimab; VBM = variant being monitored; VOC = variant of concern; WHO = World Health Organization

**1061)** 2021-12-16 CDC: CDC endorses ACIP's updated COVID-19 vaccine recommendations.  
<https://www.cdc.gov/media/releases/2021/s1216-covid-19-vaccines.html>

Today, CDC is endorsing updated recommendations made by the Advisory Committee on Immunization Practices (ACIP) for the prevention of COVID-19, expressing a clinical preference for individuals to receive an mRNA COVID-19 vaccine over Johnson & Johnson's COVID-19 vaccine. ACIP's unanimous recommendation followed a robust discussion of the latest evidence on vaccine effectiveness, vaccine safety and rare adverse events, and consideration of the U.S. vaccine supply. The U.S. supply of mRNA vaccines is abundant – with nearly 100 million doses in the field for immediate use. This updated CDC recommendation follows similar recommendations from other countries, including Canada and the United Kingdom. Given the current state of the pandemic both here and around the world, the ACIP reaffirmed that receiving any vaccine is better than being unvaccinated. Individuals who are unable or unwilling to receive an mRNA vaccine will continue to have access to Johnson & Johnson's COVID-19 vaccine.

**1062)** 2021-12-17 Cooper R: Noble lies are a public health hazard. THE WEEK, 17 Dec 2021.  
<https://theweek.com/coronavirus/1008155/noble-lies-are-a-public-health-hazard>

**1063)** 2021-12-19 LaPook J: COVID and safer holiday gatherings, 11:10 -14:57  
<https://www.cbs.com/shows/cbs-sunday-morning/video/ztOo3TeLHgXraEUXbeOmcDfzIn7BYZCX/-sunday-morning-full-episode-12-19/>

**1064)** 2021-12-19 Braver R: Dr. Francis Collins retires as NIH Director, 15:01 – 22:38, CBS News  
<https://www.cbsnews.com/video/retiring-nih-director-dr-francis-collins/>

**1065)** 2021-12-19 Collins F: Transcript: NIH Director Dr. Francis Collins on “Face the Nation,” December 19, 2021. CBSNews  
<https://www.cbsnews.com/news/transcript-nih-director-dr-francis-collins-face-the-nation-12-19-2021/>

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- 1066)** 2021-12-19 Dellatto M: Fauci: Pfizer's possibly game-changing Covid-19 pill won't be widely available for 'months.'  
<https://www.forbes.com/sites/marisadellatto/2021/12/19/fauci-pfizers-possibly-game-changing-covid-19-pill-wont-be-widely-available-for-months/?sh=1bc7e423cc30>
- 1067)** 2021-12-20 Senefeld JW, Johnson PW, Kunze KL, Bloch EM, van Helmond N, Golafshar MA, Klassen SA, Klompas AM, Sexton MA, Diaz Soto JC, Grossman BJ, Tobian AAR, Goel R, Wiggins CC, Bruno KA, van Buskirk CM, Stubbs JR, Petersen MM, Sachais BS, Buras MS, Wiczorek MA, Russoniello B, Dumont LJ, Baker SE, Vassallo RR, Shepherd JRA, Young PP, Verdun NC, Marks P, Haley NR, Katz L, Herasevich V, Waxman DA, Whelan ER, Bergman A, Clayburn AJ, Grabowski MK, Larson KF, Ripoll JG, Andersen KJ, Vogt MNP, Dennis JJ, Regimbal RJ, Bauer PR, Blair JE, Blair JE, Buchholtz ZA, Pletsch MC, Wright K, Greenshields JT, Joyner MJ, Wright RS, Carter RE, Fairweather DL: Access to and safety of COVID-19 convalescent plasma in the United States Expanded Access Program: A national registry study. PLOS Medicine 2021 December 20; 1-28.  
<https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1003872>
- 1068)** 2021-12-20 O'Shaughnessy JA: FDA EUA regarding AstraZeneca Pharmaceuticals LP's EVUSHELD for use as pre-exposure prophylaxis of COVID-19 in certain adults and pediatric individuals... Tixagevimab and Cilgavimab, the active components of EVUSHELD, are neutralizing IgG1 monoclonal antibodies that bind to distinct, non-overlapping epitopes within the receptor binding domain of the spike protein of SARS-CoV-2. EVUSHELD is an investigational drug and is not approved for any uses, including use as pre-exposure prophylaxis of COVID-19. <https://www.fda.gov/media/154704/download>
- 1069)** 2021-12-21 Kozlov M: Omicron overpowers key COVID antibody treatments in early tests—Nearly all of the monoclonal antibodies used to prevent severe disease fail to stand up to the new variant, laboratory assays show. <https://www.nature.com/articles/d41586-021-03829-0>
- 1070)** 2021-12-21 Sullivan DJ, Gebo KA, Shoham S, Bloch EM, Lau B, Shenoy AG, Mosnaim GS, Gniadek TJ, Fukuta Y, Patel B, Heath SL, Levine AC, Meisenberg BR, Spivak ES, Anjan S, Huaman MA, Blair JE, Currier JS, Paxton JH, Gerber JM, Petrini JR, Broderick PB, Rausch W, Cordisco ME, Hammel J, Greenblatt B, Cluzet VC, Cruser D, Oei K, Abinante M, Hammitt LL, Sutcliffe CG, Forthal DN, Zand MS, Cachay ER, Raval JS, Kassaye SG, Foster EC, Roth M, Marshall CE, Yarava A, Lane K, McBee NA, Gawad AL, Karlen N, Singh A, Ford DE, Jabs DA, Appel LJ, Shade DM, Ehrhardt S, Baksh SN, Laeyendecker O, Pekosz A, Klein SL, Casadevall A, Tobian AAR, Hanley DF: Randomized controlled trial of early outpatient COVID-19 treatment with high-titer.  
<https://www.medrxiv.org/content/10.1101/2021.12.10.21267485v1.full.pdf>
- 1071)** 2021-12-22 FDA: Coronavirus (COVID-19) Update: FDA authorizes first oral antiviral for treatment of COVID-19. <https://www.fda.gov/news-events/press->

[announcements/coronavirus-covid-19-update-fda-authorizes-first-oral-antiviral-treatment-covid-19](#)

- 1072)** 2021-12-22 O'Shaughnessy JA, acting FDA Chief Scientist: To Eli Lilly and Company. RE: Emergency Use Authorization 094. U.S. Food and Drug Administration. <https://web.archive.org/web/20211224034648/https://www.fda.gov/media/145801/download>

On December 22, 2021, again having concluded that revising this EUA is appropriate to protect the public health or safety under section 564(g)(2) of the Act, FDA is reissuing the December 3, 2021 letter in its entirety, to remove the limitation on the authorized use of bamlanivimab and etesevimab that previously authorized bamlanivimab and etesevimab administered together only in those states, territories, and US jurisdictions in which the combined frequency of variants resistant to bamlanivimab and etesevimab administered together is less than or equal to 5%. FDA is also revising the healthcare provider fact sheet to remove this limitation on the authorized use of bamlanivimab and etesevimab and to incorporate additional virology information.

<https://www.fda.gov/media/145801/download> January 24, 2022.

<https://www.fda.gov/media/156151/download> February 11, 2022

<https://www.fda.gov/media/143602/download> Revoked March 2, 2021

2022-05-04 ASPR Office of the Assistant Secretary for Preparedness & Response: Important Bamlanivimab/Etesevimab Updates. <https://aspr.hhs.gov/COVID-19/Therapeutics/Products/Bamlanivimab-etesevimab/Pages/default.aspx>

- 1073)** 2021-12-22 Kavanaugh: Miscellaneous Order (12/22/2021) for oral arguments before the U.S. Supreme Court on Friday, January 7, 2022 in application 21A244: NAT. FED'N OF INDEP. BUS., ET AL. V. DEPT. OF LABOR, OSHA, ET AL. and application 21A247: OHIO, ET AL. V. DEPT. OF LABOR, ET AL. [https://www.supremecourt.gov/orders/courtorders/122221zr2\\_f20h.pdf](https://www.supremecourt.gov/orders/courtorders/122221zr2_f20h.pdf)

- 1074)** 2021-12-22 Barnes R: Supreme Court sets special hearing for Biden's vaccine rules for health-care workers, private businesses. The Washington Post. [https://www.washingtonpost.com/politics/courts\\_law/biden-vaccine-mandates-supreme-court/2021/12/22/dd3bab94-6382-11ec-a7e8-3a8455b71fad\\_story.html](https://www.washingtonpost.com/politics/courts_law/biden-vaccine-mandates-supreme-court/2021/12/22/dd3bab94-6382-11ec-a7e8-3a8455b71fad_story.html)

- 1075)** 2021-12-22 Judith Dawson [judith.dawson@bjc](mailto:judith.dawson@bjc)

Subject: 12/22/21 COVID-19 Communications to Providers

Being sent to active Medical Staff, Midlevel Providers and Office Managers:

**mAB Clinic Updates:**

**mAb Therapy Exceeding Capacity:** Demands for monoclonal antibody (mAb) therapy has exceeded capacity at BJC's clinics. To triage patients during these unprecedented volumes, orders will be limited to qualifying high-risk patients who have a positive COVID-19 test. We will cease

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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*  
**Prevention:** *Active Immunization:* Vaccines

accepting adult patients for post-exposure prophylaxis at this time. For information on eligibility and ordering, please visit. [www.bjc.org/for-physicians/mab](http://www.bjc.org/for-physicians/mab)

**Expanded EUA Criteria:** Based on expanded EUA criteria, BJC HealthCare and Washington University are now able to offer monoclonal antibody therapy (mAb) to patients 0-11 years old. On Monday, December 20, 2021, St. Louis Children's Hospital began treating high-risk pediatric patients of all ages at the mAb clinic on the Washington University School of Medicine Campus as well as at the St. Louis Children's Specialty Care Center (CSCC) – South County. Please visit [www.bjc.org/For-Physicians/mab](http://www.bjc.org/For-Physicians/mab) for ordering information. ...

**1076)** 2021-12-22 O'Shaughnessy: FDA: EUA 105 letter to Pfizer regarding PAXLOID [nirmatrelvir, a SARS-CoV-2 main protease (Mpro: also referred to as 3CLpro or nsp5 protease) inhibitor, co-packaged with ritonavir, an HIV-1 protease inhibitor and CYP3A inhibitor. Ritonavir, which has no activity against SARS-CoV-2 on its own, is included to inhibit the CYP3A-mediated metabolism of nirmatrelvir and consequently increase nirmatrelvir plasma concentration to levels anticipated to inhibit SARS-CoV-2 replication. PAXLOID is not approved for any use, including treatment of COVID-19.]  
<https://web.archive.org/web/20211222180424/https://www.fda.gov/media/155049/download>

PAXLOID is comprised of nirmatrelvir, a SARS-CoV-2 main protease (Mpro: also referred to as 3CLpro or nsp5 protease) inhibitor, co-packaged with ritonavir, an HIV-1 protease inhibitor and CYP3A inhibitor. Ritonavir, which has no activity against SARS-CoV-2 on its own, is included to inhibit the CYP3A-mediated metabolism of nirmatrelvir and consequently increase nirmatrelvir plasma concentrations to levels anticipated to inhibit SARS-CoV-2 replication. PAXLOID is not approved for any use, including for use for the treatment of COVID-19.

<https://www.fda.gov/media/155049/download> (2022-04-14)

This letter is in response to Pfizer, Inc.'s (Pfizer) request that the Food and Drug Administration (FDA or Agency) issue an Emergency Use Authorization (EUA) for the emergency use of PAXLOID (nirmatrelvir co-packaged with ritonavir) for the treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in certain adults and pediatric patients pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3). On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes coronavirus disease 2019 (COVID-19). 1 On the basis of such determination, the Secretary of HHS on March 27, 2020, declared that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic, pursuant to Section 564 of the Act (21 U.S.C. 360bbb-3), subject to terms of any authorization issued under that section.2 PAXLOID is comprised of nirmatrelvir, a SARS-CoV-2 main protease (Mpro: also referred to as 3CLpro or nsp5 protease) inhibitor, co-packaged with ritonavir, an HIV-1 protease inhibitor and CYP3A inhibitor. Ritonavir, which has no activity against SARS-CoV-2 on its own, is included to inhibit the CYP3A-mediated metabolism of nirmatrelvir and consequently increase nirmatrelvir plasma concentrations to levels anticipated to inhibit SARS-CoV-2 replication. PAXLOID is not approved for any use, including for use for the treatment of COVID-19. Based on the totality of scientific evidence available to FDA, including data from the clinical trial EPIC-HR (NCT04960202), a Phase 2/3 randomized, double blind, placebo-controlled clinical trial, it is reasonable to believe that

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PAXLOVID may be effective for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing

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<sup>1</sup>U.S. Department of Health and Human Services, Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3, February 4, 2020. <sup>2</sup> U.S. Department of Health and Human Services, Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3, 85 FR 18250 (April 1, 2020).

at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death, as described in the Scope of Authorization (Section II), and when used under the conditions described in this authorization, the known and potential benefits of PAXLOVID outweigh the known and potential risks of such product. Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of PAXLOVID for the treatment of mild-to-moderate COVID-19 in certain adults and pediatric patients, as described in the Scope of Authorization section of this letter (Section II) and subject to the terms of this authorization.

**1077)** 2021-12-22 Associated Press: Experts warn of ‘perfect storm’ in Missouri as cases jump. KSHB news. <https://www.kshb.com/news/coronavirus/experts-warn-of-perfect-storm-in-missouri-as-cases-jump>

**1078)** 2021-12-22 Gilead: Gilead announces New England Journal of Medicine publication of data demonstrating Veklury (Remdesivir) significantly reduced risk of hospitalization in high-risk patients with COVID-19. –Subgroup analyses show consistently high efficacy for patients regardless of underlying medical conditions associated with higher risk for severe COVID-19 compared with placebo-- <https://www.gilead.com/news-and-press/press-room/press-releases/2021/12/gilead-announces-new-england-journal-of-medicine-publication-of-data-demonstrating-veklury-remdesivir-significantly-reduced-risk-of-hospitalization>

**1079)** 2021-12-23 Thomas K, Robbins R: Covid antibody drugs go unused as need soars. The New York Times. <https://web.archive.org/web/20201223152514/https://www.nytimes.com/2020/12/23/health/covid-antibody-treatment.html>

**1080)** 2021-12-23 Haseltine WA: Omicron evades most but fortunately not all monoclonal antibodies. Forbes Healthcare <https://www.forbes.com/sites/williamhaseltine/2021/12/23/omicron-evades-most-but-fortunately-not-all-monoclonal-antibodies/?sh=fecdf6082fec>

**1081)** 2021-12-23 O’Shaughnessy JA: EUA Letter 108 to Merck to authorize molnupiravir (a nucleoside analogue that inhibits SARS-CoV-2 replication by viral mutagenesis). <https://web.archive.org/web/20211223145523/https://www.fda.gov/media/155053/download>

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- 1082)** 2021-12-23. Tin A: FDA authorizes second COVID antiviral pill, from Merck, if no alternatives available. <https://www.cbsnews.com/news/fda-authorizes-covid-antiviral-pill-merck-molnupiravir/#>
- 1083)** 2021-12-23 FDA: Coronavirus (COVID-19) Update: FDA Authorizes additional oral antiviral for treatment of COVID-19 in certain adults. <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-additional-oral-antiviral-treatment-covid-19-certain>
- 1084)** 2021-12-23 Quinn M: Supreme Court to hear challenges to Biden COVID-19 vaccine rules for health care workers, large companies. CBS NEWS <https://www.cbsnews.com/news/supreme-court-biden-covid-19-vaccine-rules-health-care-workers-large-companies/>
- 1085)** 2021-12-23 Ellis R: Monoclonal antibody for Omicron in short supply. WEBMD news brief. <https://www.webmd.com/lung/news/20211222/monoclonal-antibody-for-omicron-in-short-supply>
- 1086)** 2021-12-23 Minnesota Department of Health: Ethical framework for allocation of Monoclonal Antibodies during the COVID-19 Pandemic. <https://web.archive.org/web/20211224142017/https://www.health.state.mn.us/diseases/coronavirus/hcp/mabethical.pdf>

This framework has been updated since 11/12/21 to clarify allocation priorities, clinical prioritization, potential for deprioritization of access for post-exposure prophylaxis (PEP) patients, and lottery considerations.

## Introduction

Since November 2020, the U.S. Food and Drug Administration (FDA) has issued Emergency Use Authorizations (EUAs) to permit the emergency use of investigational monoclonal antibody (mAb) therapies for the treatment of mild to moderate COVID-19 in adult and pediatric patients. The currently authorized mAbs are:

- Casirivimab/imdevimab (Regeneron) EUA issued Nov. 21, 2020<sup>1</sup>
- Bamlanivimab/etesevimab (Eli Lilly) EUA issued Feb. 9, 2021<sup>2</sup>
- Sotrovimab (GlaxoSmithKline LLC) EUA issued Oct. 8, 2021<sup>3</sup>

The FDA issued an EUA on Nov. 9 for the use of bamlanivimab alone for treatment of COVID-19. 2020.<sup>4</sup> As of April 16, 2021; however, this EUA has been revoked.<sup>5</sup> This revocation was issued due to concerns about the sustained increase of SARS-CoV-2 viral variants that are resistant to bamlanivimab alone, resulting in the increased risk for

treatment failure. The FDA therefore determined that the known and potential benefits of bamlanivimab, when administered alone, no longer outweigh the known and potential risks for its authorized use.

In May and June of 2021, the FDA issued updated eligibility criteria for mAb treatment for both casirivimab/imdevimab (Regeneron) and bamlanivimab/etesevimab, and authorized the addition of a subcutaneous route of administration for casirivimab/imdevimab (Regeneron) as an alternative when intravenous infusion is not feasible and would lead to delay in treatment.<sup>6</sup>

On July 30, 2021, the FDA updated the EUA for casirivimab/imdevimab (Regeneron) to authorize use of this product for post-exposure prophylaxis (PEP) in some patients.<sup>7</sup> On Sept. 16, 2021, the FDA updated the EUA for bamlanivimab/etesevimab to authorize use of this product for PEP in the same patient population as that for PEP using the Regeneron product, and with specific guidance that bamlanivimab/etesevimab would only be authorized for continued use in states where prevalent COVID-19 variants are susceptible to the mAb.<sup>8</sup>

With respect to treatment uses, the FDA has noted in the EUAs for the currently authorized mAbs:

*"Based on the totality of scientific evidence available to FDA, it is reasonable to believe that ... " these monoclonal antibody therapies "... may be effective in treating mild to moderate COVID-19 in adults and pediatric patients with positive results of direct SARS-CoV-2 viral testing who are 12 years of age or older weighing at least 40kg, and who are at high risk for progressing to severe COVID-19 and/or hospitalization, and that, when used under the conditions described in this authorization, the known and potential benefits ... when used to treat COVID-19 in such patients outweigh the known and potential risks of such product(s)."*<sup>9</sup>

The patient eligibility criteria listed in the EUA for the authorization of each of the currently authorized monoclonal antibody therapies are identical. For that reason, this document covers each of these therapies under the umbrella term "mAb." Notably, these mAbs are not authorized for patients who are hospitalized due to COVID-19 or require oxygen therapy due to COVID-19. The U.S. government has secured supplies of these investigational antibody therapies for distribution to states. Infusion facilities may order directly from the U.S. Department of Health and Human Services as needed.

Allocation and administration of these mAbs for treatment are **time-sensitive**, as the EUA for each specifies that infusions be administered as soon as possible after a positive COVID-19 test result and **within 10 days of**

**symptom onset.**<sup>10,11</sup> Consequently, communicating to health care systems, physicians, patients, and COVID-19 test sites the importance of rapid testing and referral for potential infusion is crucial. The EUA Fact Sheet states: "For treatment, intravenous infusion is strongly recommended. Subcutaneous injection is an alternative route of administration when intravenous infusion is not feasible and would lead to delay in treatment."<sup>12</sup>

For post-exposure prophylaxis (PEP) uses, the FDA notes:

*"[I]t is reasonable to believe that [the authorized mAbs] may be effective for use as post-exposure prophylaxis of COVID-19 in individuals who are at high risk for progression to severe COVID-19, including hospitalization or death, as described in the Scope of Authorization (Section II), and that, when used under [such condition], the known and potential benefits of [the authorized mAbs] outweigh the known and potential risks of such products."*<sup>13</sup>

Allocation and administration of mAbs for PEP are also time-sensitive. The EUA states that mAbs should be administered for PEP "as soon as possible following exposure to SARS-CoV-2," without providing a more specific timeframe.<sup>11</sup> **This framework recommends administering mAbs for PEP within 10 days from exposure for eligible patients who are not expected to mount an adequate immune response – e.g., those with immunocompromising conditions or on immunosuppressive medications – and administering mAbs for PEP within five days from exposure for all other eligible patients.** Thus, communicating to health care systems, physicians, and relevant groups of patients about the option of accessing mAbs for PEP is crucial. For PEP, mAbs may be administered either via infusion or subcutaneous injection.<sup>12</sup>

On Sept. 3, 2021, the National Institutes of Health (NIH) COVID-19 Treatment Guidelines Panel issued guidance outlining clinical prioritization when there is insufficient capacity to meet need for mAbs.<sup>14</sup> **MCEC recommends a somewhat different approach to allocation in scarcity, which is outlined below.** The NIH panel's guidance recommends prioritizing treatment uses of mAbs over all PEP. This MDH framework **prioritizes PEP for highly immunocompromised individuals** (as specified on Page 9) **along with treatment uses, over PEP for immunocompetent individuals**, for two reasons. First, highly immunocompromised individuals face extremely high risk of progression to severe COVID-19. Second, unlike immunocompetent individuals, immunocompromised patients who develop COVID-19 infection may progress to severe disease too quickly to reasonably allow them to access mAbs for treatment. Thus, to adequately protect this population, PEP for immunocompromised individuals should be managed differently than PEP for immunocompetent individuals. In addition, the NIH panel's guidance recommends prioritizing "unvaccinated or incompletely vaccinated individuals" over vaccinated ones in allocation of mAbs (as well as prioritizing vaccinated individuals who are immunocompromised). In allocating mAbs for treatment of COVID-positive patients, this MDH framework deviates from that guidance by permitting the **prioritization of both vaccinated and unvaccinated individuals who are at very high risk of progression to severe COVID-19**, even if they are not immunocompromised.

**This document provides ethical guidance regarding the allocation of mAbs.** When the first mAb – bamlanivimab – was first made available through an EUA, it was anticipated that supply would be insufficient to meet need. The Minnesota Department of Health (MDH) and the Minnesota COVID-19 Ethics Collaborative (MCEC) developed Interim Ethical Guidance for Monoclonal Antibody Administration. That and subsequent versions of this guidance document are now superseded by this framework.

This document was developed by MDH working with a subgroup of the MCEC, including the co-leads, with additional clinical input, and was subsequently reviewed by MCEC. The document addresses relevant past guidance developed at MDH, key ethical values, and how allocation should occur both under conditions of scarcity and conditions of sufficient supply regarding: (1) allocation to hospitals and health systems throughout the state and (2) allocation among patients within each infusion or injection facility (which will initially be affiliated with hospitals).

**MCEC recommends this ethical guidance be operationalized using a centralized system called the Minnesota Resource Access Platform (MNRAP).** This centralized approach promotes consistency among institutions and systems across the state of Minnesota, which is ethically important because it:

- Enhances transparency and the trustworthiness of pandemic response throughout the state;
- Fosters a common standard of care and access, and so helps to ensure fairness; and
- Promotes equity in allocation for all Minnesotans, whether or not they are affiliated with a health system.

After adopting this framework in February 2021, and after requests from a small number of health care systems, MDH decided to permit some health systems to opt out of using MNRAP to allocate mAbs on the condition that these systems demonstrate that their allocation process meets the ethical requirements of this framework and is at least as fair and equitable as MNRAP. These conditions require that opted-out systems accept unaffiliated patients without disadvantaging them, and that they implement their own lottery process when their system is in scarcity, as defined either by insufficient doses or appointment slots to meet demand. The weighted lottery process should account for the same clinical and nonclinical factors as outlined in this guidance (refer to “Escalating approaches to scarce resource allocation” below for those specific requirements). Opted-out systems should also meet additional reporting requirements set by MDH to demonstrate their respective systems are performing as intended. **Given the current state of mAb supply, there is the possibility that mAbs may need to be rationed due to scarcity. Thus, all systems that have not opted out of MNRAP should use MNRAP for all mAbs allocation decisions, and not supplement MNRAP with allocation processes internal to their respective systems.** In other words, all patients for facilities that have not opted out of MNRAP should be run through the MNRAP system.

**1087)** 2021-12-27 The National Law Review: Will answers come in 2022? Supreme Court sets January 7 hearing on COVID Vaccine Mandates.

<https://www.natlawreview.com/article/will-answers-come-2022-supreme-court-sets-january-7-hearing-covid-vaccine-mandates>

**1088)** 2021-12-27 CDC: CDC updates and shortens recommended isolation and quarantine period for general population. <https://www.cdc.gov/media/releases/2021/s1227-isolation-quarantine-guidance.html>

**1089)** 2021-12-28 Villapando N, Villalpando R: Texas runs out of monoclonal antibody treatment to fight omicron variant of COVID-19. USA TODAY <https://www.usatoday.com/story/news/nation/2021/12/28/texas-runs-out-monoclonal-antibody-sotrovimab-treatment-fight-omicron-covid/9031897002/>

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- 1090)** 2021-12-28 Jacqueline A. O'Shaughnessy, Ph.D., Acting Chief Scientist, FDA, U.S. Food & Drug: Letter to Dawn O'Connell, Assistant Secretary for Preparedness and Response, Office of Assistant Secretary for Preparedness and Response, Office of the Secretary, U.S. Department of Health and Human Services: Most recent EUA Letter regarding COVID-19 Convalescent Plasma, **December 28, 2021.**  
<https://www.fda.gov/media/141477/download>
- 1091)** 2021-12-29 Dorman JL: Former Surgeon General Jerome Adams says CDC officials wouldn't follow the new guidance 'for their own family.' INSIDER  
<https://www.businessinsider.com/jerome-adams-criticizes-cdc-guidance-isolation-covid-19-antigen-tests-2021-12>
- 1092)** 2021-12-30 NIH COVID-19 Treatment Guidelines: The COVID-19 treatment guidelines panel's statement on therapies for high-risk, nonhospitalized patients with mild to moderated COVID-19.  
<https://www.covid19treatmentguidelines.nih.gov/therapies/statement-on-therapies-for-high-risk-nonhospitalized-patients/>
- 1093)** 2021-12-30 McCammon S, Doucleff M: Omicron causes record-breaking COVID cases in the U.S. and globally. NPR 2021 Dec. 30  
<https://www.npr.org/2021/12/30/1069027394/omicron-causes-record-breaking-covid-cases-in-the-u-s-and-globally>
- 1094)** 2021-12-30 Quintana A: Florida surgeon general unhappy with fed's distribution of monoclonal antibody treatments. WTSP 10 Tampa Bay  
<https://www.wtsp.com/article/news/regional/florida/florida-surgeon-general-monoclonal-antibody-treatment/67-0ad20411-2b32-41ad-bcb2-15d07c5cfc7c>
- 1095)** 2021-12-31 FDA: FDA authorizes first two oral antivirals for treatment of COVID-19 | EUA for COVID-19 treatments and tests  
<https://content.govdelivery.com/accounts/USFDA/bulletins/30221ce>
- 1096)** 2022-01-03 Anthes E: How accurate are at-home Covid test? Here's a quick guide. The New York Times.  
<https://web.archive.org/web/2022010163820/https://www.nytimes.com/article/at-home-covid-tests-accuracy.html>
- 1097)** 2022-01-03 Jewett C: With no way to identify Omicron and Delta patients, treatment decisions are vexing doctors. The New York Times.  
<https://www.nytimes.com/2022/01/03/health/doctors-omicron.html>
- 1098)** 2022-01-04 CDC: Understanding mRNA COVID-19 Vaccines.  
<https://www.cdc.gov/TemplatePackage/contrib/widgets/micrositeCollectionViewerMed/index.html?chost=www.muw.edu&cpath=/disease/cdcinfo&csearch=&chash=!%2Fdetail%2F40>

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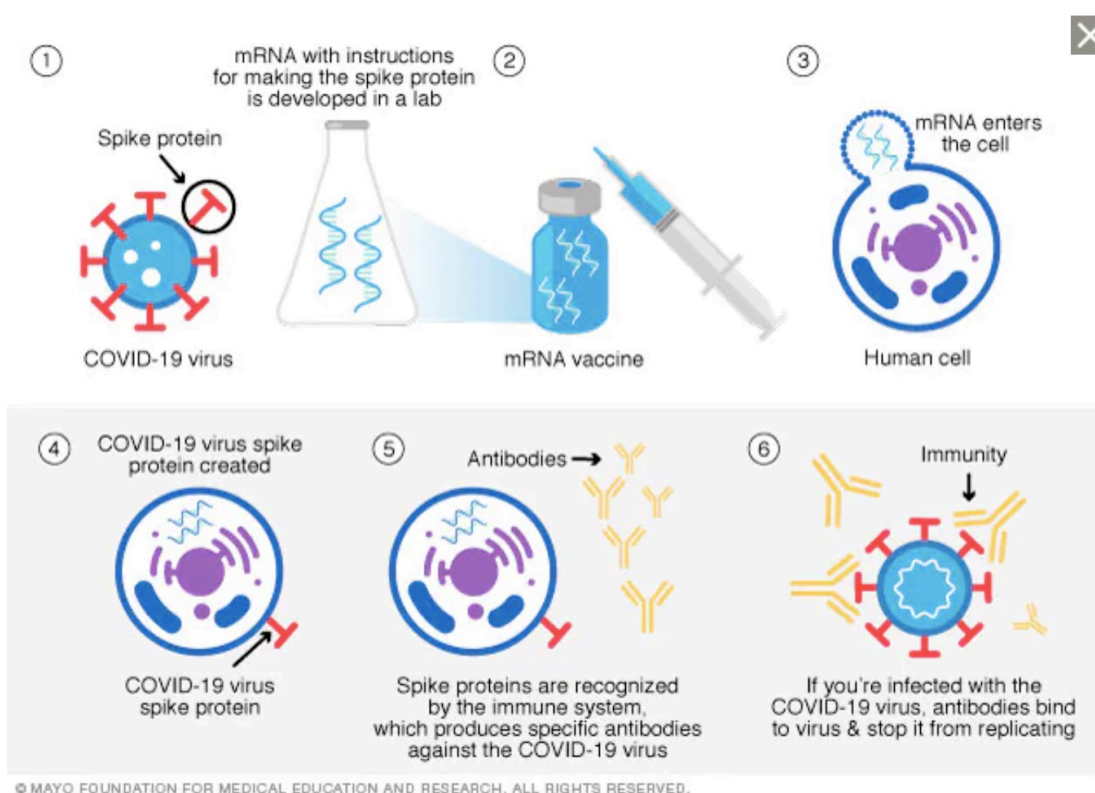
[6795&ctitle=COVID-19%20CDC%20Info%20-%20Disease%20Outbreak%20Information%20-%20MUW&wn=micrositeCollectionViewerMed&wf=/TemplatePackage/contrib/widgets/micrositeCollectionViewerMed/&wid=micrositeCollectionViewerMed1&mMode=widget&mpage=&mChannel=&cdcCollectionid=403305&cdcTheme=theme1&cdcGeotag=%7B%27continent%27:%20%276255149%27,%20%27country%27:%20%276252001%27,%20%27state%27:%20%274436296%27,%20%27region%27:%20%274434357%27%20%7D&cdcDataid=404908&chashOptMode=out#!/detail/413605](https://www.cdc.gov/media/releases/2022/s0104-covid-19-pfizer.html)

- 1099)** 2022-01-04 Cook S, Watson K: U.S. doubling and accelerating order Pfizer antiviral pills. CBS News <https://www.cbsnews.com/news/biden-pfizer-covid-pill-antiviral-double-shipment/>
- 1100)** 2022-01-06 Biden J: President Biden blasts Trump for ‘spreading a web of lies’ in a Jan. 6, 2022 speech. <https://www.youtube.com/watch?v=bUfyXBmp7S8>
- 1101)** 2022-01-07 Yek C, Warner S, Wiltz JL, Sun J, Adjei S, Mancera A, Silk BJ, Gundlapalli AV, Harris AM, Boehmer TK, Kadri SS: Risk factors for severe COVID-19 outcomes among persons aged  $\geq 18$  years who completed a primary COVID-19 vaccination series – 465 Health Care facilities, United States, December 2020–October 2021. CDC, Morbidity and Mortality Weekly Report (MMWR) <https://www.cdc.gov/mmwr/volumes/71/wr/mm7101a4.htm>
- Among 1,228,664 persons who completed primary vaccination during December 2020–October 2021, severe COVID-19–associated outcomes (0.015%) or death (0.0033%) were rare. Risk factors for severe outcomes included age  $\geq 65$  years, immunosuppressed, and six other underlying conditions. All persons with severe outcomes had at least one risk factor; 78% of persons who died had at least four.
- 1102)** 2022-01-11 American Red Cross: Red Cross declares first-ever blood crisis amid omicron surge. <https://www.redcross.org/about-us/news-and-events/press-release/2022/blood-donors-needed-now-as-omicron-intensifies.html>
- 1103)** 2022-01-12 Minnesota Department of Health: Ethical framework for allocation of Monoclonal Antibodies during the COVID-19 Pandemic. <https://www.health.state.mn.us/diseases/coronavirus/hcp/mabethical.pdf>
- 1104)** 2022-01-13 de Vogue A: Supreme Court blocks nationwide vaccine and testing mandate for large businesses, allows health care worker vaccine mandate to take effect. <https://www.cnn.com/2022/01/13/politics/supreme-court-vaccine-mandate-covid-19/index.html>
- 1105)** 2022-01-18 Mayo Clinic Staff: Different types of COVID-19 vaccines: How they work. <https://www.mayoclinic.org/diseases-conditions/coronavirus/in-depth/different-types-of-covid-19-vaccines/art-20506465> ;

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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*  
**Prevention:** *Active Immunization:* Vaccines

## mRNA vaccine cartoon:



## mRNA vaccine

A mRNA vaccine is made using mRNA that gives your cells instructions for how to make the spike protein found on the surface of the COVID-19 virus. After vaccination, your immune cells begin making the spike protein and displaying them on cell surfaces. This causes your body to create antibodies that can fight the COVID-19 virus.

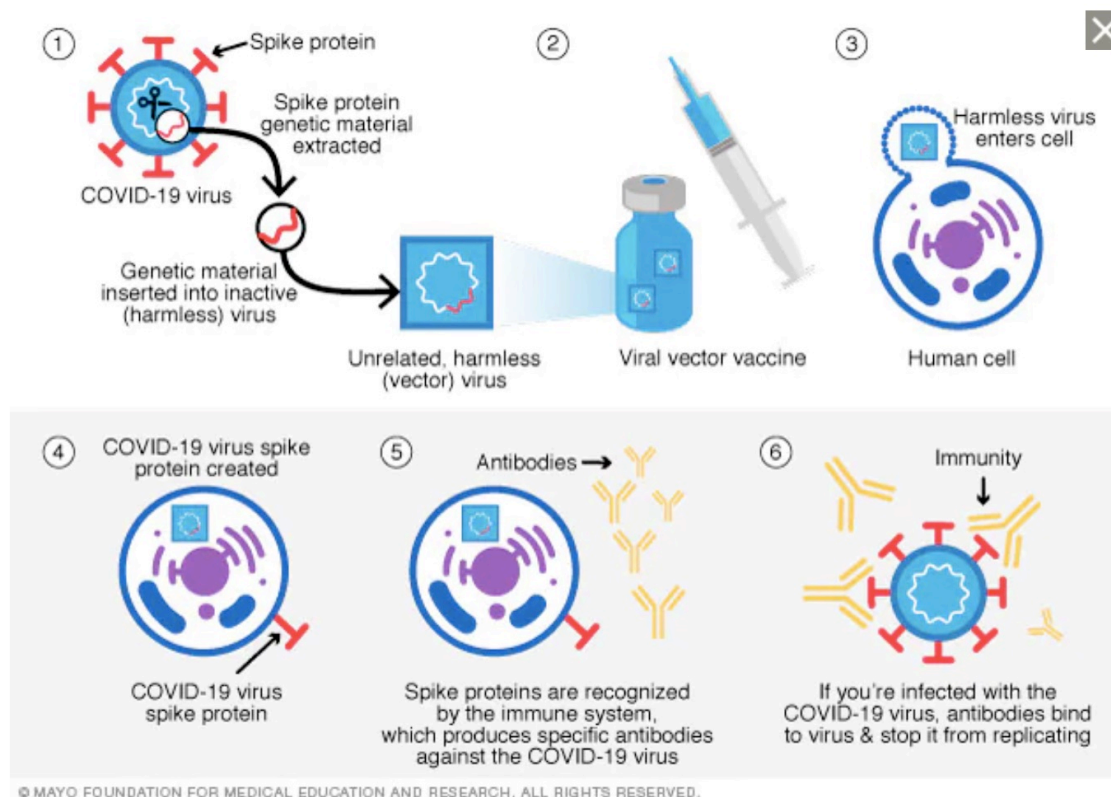
<https://www.mayoclinic.org/diseases-conditions/coronavirus/in-depth/different-types-of-covid-19-vaccines/art-20506465#dialogId29607008> ;

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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*  
**Prevention:** *Active Immunization:* Vaccines

## Viral vector vaccine



## Viral vector vaccine

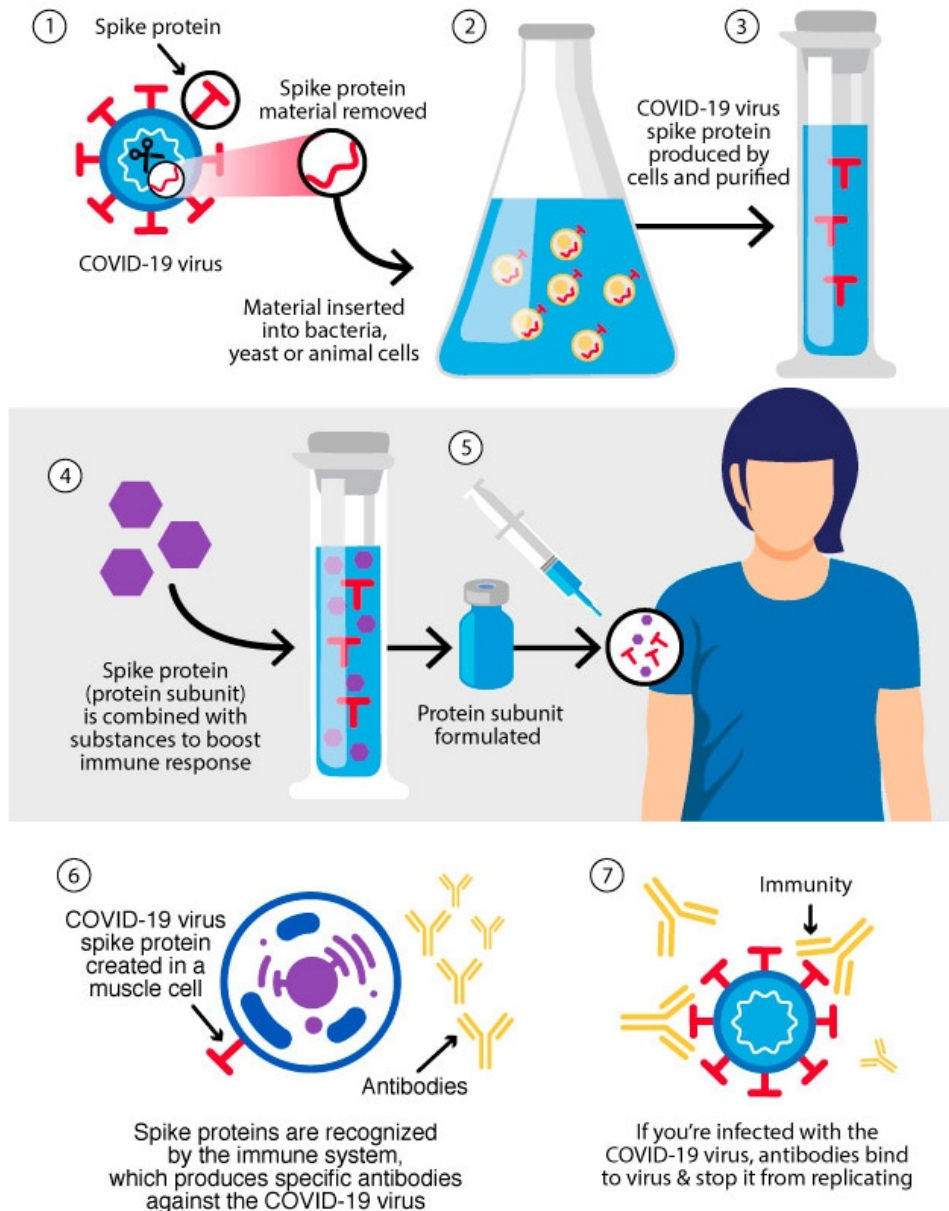
A viral vector vaccine is made when genetic material from a COVID-19 virus is inserted into a unrelated, harmless virus. When the viral vector gets into your cells, it delivers genetic material from the COVID-19 virus that gives your cells instructions for how to make the spike protein found on the surface of the COVID-19 virus. Once your cells displace the spike proteins on their surfaces, your immune system creates antibodies that can fight the COVID-19 virus.

<https://www.mayoclinic.org/diseases-conditions/coronavirus/in-depth/different-types-of-covid-19-vaccines/art-20506465#dialogId17927109> ;

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**Prevention:** *Active Immunization:* Vaccines

## Protein subunit vaccine:



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## Protein subunit vaccine

Subunit vaccines include only the parts of a virus that best stimulate your immune system. This type of COVID-19 vaccine contains harmless S proteins. Once your immune system recognizes the S proteins, it creates antibodies and defensive white blood cells. If you later become infected with the COVID-19 virus, the antibodies will fight the virus.

<https://www.mayoclinic.org/diseases-conditions/coronavirus/in-depth/different-types-of-covid-19-vaccines/art-20506465#dialogId5857171>

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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*

**Prevention:** *Active Immunization:* Vaccines



- 1106)** 2022-01-18 Exact Sciences Corp: Exact sciences presents data showing improved accuracy of second-generation Cologuard test and progress toward an even better colorectal cancer screening solution for patients.  
<https://investor.exactsciences.com/investor-relations/press-releases/press-release-details/2022/Exact-Sciences-Presents-Data-Showing-Improved-Accuracy-of-Second-generation-Cologuard-Test-and-Progress-Toward-an-Even-Better-Colorectal-Cancer-Screening-Solution-for-Patients/default.aspx>
- 1107)** 2022-01-19 NIH COVID-19 Treatment Guidelines: The COVID-19 Treatment Guidelines Panel’s Statement on therapies for high-risk, nonhospitalized patients with mild to moderate COVID-19. <https://www.covid19treatmentguidelines.nih.gov/therapies/statement-on-therapies-for-high-risk-nonhospitalized-patients/>
- 1108)** 2022-01-21 O’Shaughnessy JA: FDA letter to Gilead Sciences, Inc. ...On January 21, 2022, FDA approved a supplemental application to NDA 214787 for Veklury expanding the approved uses to include the treatment of COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg), with positive results of direct SARS-CoV-2 viral testing, who are not hospitalized and have mild-to-moderate COVID-19, and who are at high risk for progression to severe COVID-19, including hospitalization or death. ...now authorizing Veklury for the treatment of COVID-19 in pediatric patients weighing 3.5 kg to less than 40 kg or pediatric patients less than 12 years of age weighing at least 3.5 kg, with positive results of direct SARS-CoV-2 viral testing, who are hospitalized, or are not hospitalized and have mild-to-moderate COVID-19, and are at high risk for progression to severe COVID-19, including hospitalization or death.  
<https://www.fda.gov/media/137564/download>
- 1109)** 2022-01-21 FDA: FDA takes actions to expand use of treatment for outpatients with mild-to-moderate COVID-19. <https://www.fda.gov/news-events/press-announcements/fda-takes-actions-expand-use-treatment-outpatients-mild-moderate-covid-19>
- 1110)** 2022-01-24 Regeneron: U.S. Food and Drug Administration revises Emergency Use Authorization for REGEN-COV® (casirivimab and imdevimab) antibody cocktail due to Omicron Variant. <https://investor.regeneron.com/static-files/cf13b06f-b874-4910-b583-c3c93c67a8f8>
- 1111)** 2022-01-24 O’Shaughnessy JA: EUA 094 letter to Eli Lilly and Company to limit the use of Eli Lilly’s monoclonal antibody cocktail due to resistance of omicron variant.  
<https://www.fda.gov/media/145801/download> ...On January 24, 2022, again having concluded that revising this EUA is appropriate to protect the public health or safety under section 564(g)(2) of the Act, FDA is reissuing the December 22, 2021 letter in its entirety, to further limit the use of bamlanivimab and estesevimab administered together for treatment of COVID-19 or as post-exposure prophylaxis of COVID-19 to exclude geographic regions

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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*  
**Prevention:** *Active Immunization:* Vaccines



where , based on available information including variant susceptibility to these drugs and regional variant frequency, infection, or exposure is likely due to a variant that is non-susceptible to bamlanivimab and etesvimab. Corresponding revisions have also been made to the authorized Fact Sheets.

- 1112)** 2022-01-24 Murphy J: Fauci expects most states to reach peak omicron by February. Close to half already have. NBC News—The Data Point  
<https://www.nbcnews.com/news/all/fauci-omicron-surge-february-2022-states-n1287935>

- 1113)** 2022-01-24 U.S. Food & Drug: Coronavirus (COVID-19 update: FDA limits use of certain monoclonal antibodies to treat COVID-19 Due to the Omicron variant.  
<https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-limits-use-certain-monoclonal-antibodies-treat-covid-19-due-omicron>

- 1114)** 2022-01-24 Alu A, Chen L, Lei H, Wei Y, Tian X, Wei X: Intranasal COVID-19 vaccines: From bench to bed. The Lancet 2022 Feb 1; 76, 103841.  
[https://www.thelancet.com/journals/ebiom/article/PIIS2352-3964\(22\)00025-1/fulltext](https://www.thelancet.com/journals/ebiom/article/PIIS2352-3964(22)00025-1/fulltext)

- 1115)** 2022-01-25 Blake A: DeSantis, conservatives erupt over FDA pulling monoclonal antibodies shown to be ineffective against omicron. The Washington Post.  
<https://www.washingtonpost.com/politics/2022/01/25/conservatives-led-by-desantis-erupt-over-another-unproven-coronavirus-treatment/>

...The Food and Drug Administration announced Monday that it would halt emergency-use authorizations for two monoclonal antibody therapies, one made by Regeneron Pharmaceuticals and one by Eli Lilly. At least with these monoclonal antibodies, unlike hydroxychloroquine and ivermectin, there was evidence they were once quite effective; that's just not the situation we find ourselves in at this point.

The FDA decision has led to a vehement outcry from some on the right, including the Republican who has most forcefully promoted monoclonal antibodies: Florida Gov. Ron DeSantis.

DeSantis said Monday that President Biden “has forced medical pros to choose treating their patients or breaking the law.”

The governor added Tuesday morning, “Without a shred of clinical data to support its decision, the Biden Administration has revoked the emergency use authorization for lifesaving monoclonal antibody treatments.”

DeSantis’s criticism has been cheered and echoed by many on the right, including Fox News’s Sean Hannity.

Going quite a bit further, DeSantis spokeswoman Christina Pushaw on Monday night even pointed a claim by a conservative conspiracy theorist that “the FDA is trying to make it so that people in Florida die of Covid. They’ll kill people to harm Republicans.” By Tuesday morning, she promoted another baseless claim that the decision was made “so Fauci-Pfizer can get a few extra points in the stock market.”

...As Nature reported more than a month ago, preliminary studies suggested that monoclonal antibody therapies, including the ones the FDA has not halted, showed virtually no efficacy against the omicron variant. <https://www.nature.com/articles/d41586-021-03829-0>

Here are some excerpts from one of the studies, which cites the Regeneron therapy (casirivimab and imdevimab) and the Eli Lilly therapy (bamlanivimab and estesevimab):...

- 1116)** 2022-01-25 U.S. Food and Drug Administration: Emergency Use Authorization. <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>
- 1117)** 2022-01-25 Troxel AB, Petkova E, Goldfeld K, Liu M, Tarpey T, Wu Y, Wu D, Agarwal A, Avendano-Solá, Brainbridge E, Bar KJ, Devos T, Duarte RF, Gharbharan A, Hsue PY, Kumar G, Luetkemeyer AF, Mayfroidt G, Nicola AM, Mukherjee A, Ortigoza MB, Pirofski LA, Rijders BJA, Rokx C, Sancho-Lopez A, Shaw P, Tebas P, Yoon HA, Grudzen C, J Association of convalescent plasma treatment with clinical status in patients hospitalized with COVID-19, A meta-analysis. JAMA Network | Open. 2022 January 25; 5(1): e2147331: 1-15. <https://web.archive.org/web/20220203022011/https://jamanetwork.com/journals/jamanetwor/open/fullarticle/2788377>
- 1118)** 2022-01-25 Tin A: How can I get Paxlovid, the COVID-19 pill? Access to COVID treatments remains a challenge. CBS News. <https://www.cbsnews.com/news/covid-19-paxlovid-pill-monoclonal-antibodies-treatments/>
- 1119)** 2022-01-27 FDA: Know your treatment options for COVID-19. <https://www.fda.gov/consumers/consumer-updates/know-your-treatment-options-covid-19>
- 1120)** 2022-01-27 Gottlieb RL, Vaca CE, Paredes R, Mera J, Webb BJ, Perez G, Oguchi G, Ryan P, Nielsen BU, Brown M, Hidalgo A, Sachdeva Y, Mittal S, Osiyemi O, Skarbinski J, Juneja K, Hyland RH, Osinusi A, Chen S, Camus G, Abdelghany M, Davies S, Behnen-arenton N, Duff F, Marty FM, Katz MJ, Ginde AA, Brown SM, Schiffer JT, and Hill JA for the GS-US-540-9012 (PINETREE) Investigators. Early Remdesivir to prevent progression to severe Covid-19 in outpatients. New Engl J Med 2022 Jan 27; 386 (4): 305-315. <https://www.nejm.org/doi/full/10.1056/NEJMoa2116846> with Supplementary Appendix [https://www.nejm.org/doi/suppl/10.1056/NEJMoa2116846/suppl\\_file/nejmoa2116846\\_appendix.pdf](https://www.nejm.org/doi/suppl/10.1056/NEJMoa2116846/suppl_file/nejmoa2116846_appendix.pdf)
- 1121)** 2022-02 Paneth N, Casadevall A, Pirofski L, Henderson JP, Grossman BJ, Shoham S, Joyner MJ: WHO covid-19 drugs guideline: reconsider using convalescent plasma. BMJ 2022 February; 376: o295. <https://www.bmj.com/content/376/bmj.o295>
- 1122)** 2022-02 Alu A, Chen L, Yuquan HL, Tian WX, Wei X: Intranasal COVID-19 vaccines: From bench to bed. [www.thelancet.com](http://www.thelancet.com) 2022 Feb; 76: 1-16. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8785603/pdf/main.pdf>

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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*  
**Prevention:** *Active Immunization:* Vaccines

- 1123) 2022-02-01 NIH: COVID-19 Treatment Guidelines: Anti-SARS-CoV-2 Monoclonal Antibodies. <https://www.covid19treatmentguidelines.nih.gov/therapies/anti-sars-cov-2-antibody-products/anti-sars-cov-2-monoclonal-antibodies/>
- 1124) 2022-02-03 IDSA Guideline on the Treatment and Management of COVID-19: Convalescent Plasma. <https://www.idsociety.org/globalassets/idsa/practice-guidelines/covid-19/treatment/idsa-covid-19-gl-tx-and-mgmt---convalescent-plasma-2022-02-03.pdf>
- 1125) 2022-02-06 Gastroenterology consultants of San Antonio: The truth about Cologuard tests. <https://www.gastroconsa.com/the-truth-about-cologuard-tests/>
- 1126) 2022-02-11 O'Shaughnessy JA: FDA EUA letter to Eli Lilly and Company: Bebtelovimab is a neutralizing IgG1 monoclonal antibody that binds to an epitope within the receptor binding domain of the spike protein of SARS-CoV-2. Betelovimab is not FDA approved for any uses, including use as treatment for COVID-19. <https://www.fda.gov/media/156151/download>
- 1127) 2022-02-11 FDA News Release: Coronavirus (COVID-19) update: FDA authorizes new monoclonal antibody for treatment of COVID-19 that retains activity against omicron variant. <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-new-monoclonal-antibody-treatment-covid-19-retains#:~:text=The%20FDA%20is%20carefully%20monitoring,2%20omicron%20subvariant.>
- 1128) 2022-02-14 Forman R: COVID Booster goes to the nasal cavity, where it will be most effective—Iwasaki A. Yale School of Medicine. <https://medicine.yale.edu/news-article/nasal-approach-to-covid-vaccination-gains-traction-at-yale/>
- 1129) 2022-02-15 Herscher M: Nearly half of state mask mandates have ended in the past 3 weeks. NBC News –The Data Point. <https://www.nbcnews.com/news/us-news/mask-mandate-map-february-2022-n1289093>
- 1130) Ducharme J: Nasal vaccines could help stop COVID-19 from spreading – If scientists can get them right. TIME. <https://time.com/6148257/nasal-vaccines-covid-19/>
- 1131) 2022-02-16. Andrus CH: Thank you letter to Gilead Sciences for providing the reference regarding the date of completion of Phase 1 remdesivir trial.

**From:** Charles.Andrus@va.gov,  
**To:** Public\_affairs@gilead.com,  
**Cc:** Charles.Andrus@va.gov, candrus600@aol.com, Anthony.Fauci@nih.hhs.gov, kara.harris@nih.hhs.gov, Janet.Woodcock@fda.hhs.gov, Denise.Hinton@hhs.gov, Jacqueline.OShaughnessy@fda.hhs.gov, michael.hogan@va.gov,  
**Subject:** RE: Phase 1 remdesivir trial result  
**Date:** Wed, Feb 16, 2022 3:25 pm  
**Attachments:** 3 Andrus SLU cv 8\_11\_2021.docx (7964K),

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**Treatment:** *Passive Immunization:* COVID-19 Convalescent Plasma and Antibodies and *Antivirals*  
**Prevention:** *Active Immunization:* Vaccines

2/16/2022

NIAID Case #12276

Dear Gilead:

Thank you for forwarding this article to me: Humeniuk R, Mathias A, Huyen C, Osinusi A, Shen G, Chng E, Ling J, Wu A, German P: Safety, Tolerability, and Tolerability, and Pharmacokinetic of Remdesivir, An antiviral for Treatment of COVID-19, in Healthy Subjects. Clin Transl Sci 2020; 13, 896-906: [Safety, Tolerability, and Pharmacokinetics of Remdesivir, An Antiviral for Treatment of COVID 19, in Healthy Subjects \(wiley.com\)](#). I have attached a copy of my CV so you know who I am. Over my decades of involvement with the Veterans Health Administration (VHA), U.S. Department of Veterans, I have attempted to be an advocate for each and every individual Veteran patient that presented to me. My biggest challenge was to have the phrase in VHA Handbook 1400.1 on Resident Supervision revised (after ~50 years): **Level 3: Attending Surgeon not present, immediately available**. What was condoned by the inappropriate application of Level 3 was that on nights, weekends, holidays, family get togethers, etc., some University Attending Surgeons would staff residents in the OR from afar (ghost surgery). Twenty years ago, I fought for that change all the way to the U.S. Court of Appeals for the Federal Circuit in *Andrus v VA*, Case 03-3162—in which the court *per curiam* “failed to rule.” I lost all my battles with the VA; but, in the end, all Attending Surgeons-of-Record in the VA today are required to be present in the OR suite during every individual Veterans’ operation which is definitely to the betterment of every Veteran patient. The VA saved face by: 1.) changing VAH Handbook from 1400.1 to VAH Handbook 1400.01 so you can’t find previous versions electronically if you don’t know the previous URL.; 2.) as is common practice today, in the agencies of the Executive Branch of the Federal Government, electronically overwrite documents without designating what has been rescinded or that there was even a previous document; and 3.) I became and still am an *unperson* in the VA from 4/1982-8/2016 since my Official Personnel File (OPF) has been misplaced/lost. Thus, from April 1982 to August 2016, I don’t exist in the VA until I returned in August 2016, as an Attending Physician and General Surgeon at the St. Louis VAMC. My VA service from 1982 to 2002 does not exist “officially” even though from 8/1996 to 1/2002, I was the Chief of Surgery, Edward Hines, Jr. VAH (the first hospital of the University-VA affiliation in 1946 under PL-79-293); and I was interviewed for the position of Under Secretary for Health

(USH) of the Veterans Health Administration (VHA), U.S. Department of Veterans Affairs (DVA) on the 10<sup>th</sup> floor of VACO (across Lafayette Square from *The White House*) on the afternoon of December 10, 1999. I am telling you this, so I can put in context for you the convoluted process regarding Remdesivir that parallels that which occurred to me in my fight to stop Physically Unsupervised resident surgeons by VA misdirection and obfuscation twenty years ago. Today, by changing URLs, electronic overwriting, and semantics, the FDA, the NIH, the CDC, the VA, etc. have somewhat stretched the truth before the American people.

I thank you for forwarding the reference regarding the Phase I studies completed for Remdesivir (RDV). As is quoted in the article:

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**Treatment:** Passive Immunization: COVID-19 Convalescent Plasma and Antibodies and Antivirals  
**Prevention:** Active Immunization: Vaccines

On May 1, 2020, based on available data from to global clinical trials, the US Food and Drug Administration (FDA) granted emergency use authorization to allow RDV to treat adults and children hospitalized with severe COVID-

19<sup>19,22,23</sup> Based on these clinical data, RDV has been approved for the treatment of adults and pediatric patients in

Japan.<sup>24</sup> This paper describes the safety and pharmacokinetics (PKs) of the solution and lyophilized formulations of i.v. RDV administered to healthy participants in the two first-in-human (FIH) phase I studies.

The above paragraph suggests that the FDA issued the EUA after review of the two first-in-human phase I studies involving Remdesivir (VEKLURY) and that review occurred at least by May 1, 2020, which means that phase I human trials were deemed safe and implies that the phase I trials *de facto* were completed—BUT, that presented multiple ethical and legal dilemmas for the FDA, the NIH, etc.

1. The FDA issued the first Remdesivir EUA on May 1, 2020 (which was the date when Dr. Fauci announced Remdesivir from the Oval Office); yet by making it an EUA, Remdesivir,-- the FDA was defining Remdesivir as an “unapproved” drug in the treatment of COVID-19

2. As phase II/III clinical trials proceeded, prospective participants who had contracted COVID-19 should have been made aware in their Informed Consent that with The Right to Try Act, PL-115-176 that they could still be afforded Remdesivir by non-participation in the mandated RCT placebo trials—for that matter, all of America should have been told of this by the FDA! As the Phase I studies *de facto* were completed, any American could have asked for Remdesivir under PL-115-176 and should have received it!

3. As I am sure that you are well-aware that Remdesivir is “a single diastereomeric monophoramidate prodrug that inhibits viral RNA polymerases” which works best during the initial viremic phase of COVID-19—rather than in the later severe disease phases of cytokine cascade and bradykinin storm. Unfortunately, with the issuance of the EUA on May 1, 2020, “the US Food and Drug Administration (FDA) granted emergency use authorization to allow RDV to treat adults and children hospitalized with severe COVID-19<sup>19,22,23</sup>.” In fact, the **FDA removed the severity stipulation quietly**--not notifying the American public of this significant retraction--on **August 28, 2020**. In the FDA January 21, 2022 letter to Madelyn Low, MBS, Manager, Regulatory Affairs, Gilead Sciences, Inc., <https://www.gilead.com/-/media/files/pdfs/remdesivir/eua-fda-authorization-letter.pdf?la=en&hash=FD3737583BE0E4DF710ADB36AEAA2DBD>, there are 8 references on pages 1 and 2 in which the Acting Chief Scientist of FDA outlined the chronology regarding Remdesivir including the August 28, 2020 retraction of the severity of illness stipulation: “...FDA revised authorized use of Veklury to no longer limit its use for the treatment of patients with severe disease.” (How could Remdesivir being an “unapproved” drug in the treatment of COVID-19 under the FDA’s EUAs standards become a drug that the FDA was officially revising authorization so it could be given early in the course of the disease? It seems like a bunch of semantics; but if that bunch of semantics limits the rights of individuals in America, that is wrong.



4. “On October 22, 2020, FDA also approved NDA 214787 for Veklury for the treatment of COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 Kg) **requiring hospitalization.**” At this point, Remdesivir (VEKLURY) was designated by the FDA as a prescription drug (NDA 214787) on October 22, 2020.

5. In November 2020, the Veterans Health Administration (VHA) of the U.S. Department of Veterans Affairs issued for the fully-FDA- authorized-prescription drug, VEKLURY, NDA 214787 the: “Remdesivir (VEKLURY) Criteria for Use” of how to administer Remdesivir with the severity Inclusion Criteria exclusively included that had been removed previously on August 28, 2020 by the FDA:

Remdesivir (VEKLURY) CFU

Remdesivir (VEKLURY) CFU

Remdesivir (VEKLURY)

Criteria for Use

November 2020

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of this document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

See the VA National PBM-MAP-VPE Monograph on this drug at [www.pbm.va.gov](http://www.pbm.va.gov) or <http://vaww.pbm.va.gov> for further information.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive remdesivir

☐

Treated for COVID-19 as an outpatient

☐

AST or ALT > 5 times the upper limit of normal

☐

Hospitalized patients but NOT requiring supplemental oxygen\*

☐

Concomitant use of hydroxychloroquine or chloroquine

☐

Current eGFR < 30 mL/min\*\*

Inclusion Criteria

The following must be fulfilled in order to meet criteria for remdesivir

☐

Hospitalized with SEVERE COVID-19 (room air oxygen saturation < 94%, requiring supplemental oxygen or increase from baseline if on chronic oxygen therapy or is requiring invasive or non-invasive ventilation or ECMO)\*\*\*

Supplemental Information

Recommended initial duration of therapy is 5 days, with the potential to extend to 10 days in patients who are not improving or who remain critically ill. Therapy can be discontinued when the patient is appropriate for discharge, even if the full duration of therapy has not been given

\*Use in hospitalized patients with mild to moderate COVID-19 at high risk for progression to severe disease may be appropriate and should be adjudicated on a case by case basis

\*\*Patients with eGFR < 30 mL/min (or CrCl < 30-50 mL/min depending on the trial) were excluded from clinical trials and routine use is not recommended by the manufacturer. Use may be considered and adjudicated on a case by case basis if the benefit is felt to outweigh the risks, especially when renal function is likely to improve rapidly (e.g. dehydration). The mechanism of calculating renal function can be based on local guidance.

\*\*\*Remdesivir alone is not recommended alone for patients on mechanical ventilation or ECMO but may be considered in conjunction with corticosteroids in patients who have recently been intubated, according to the NIH Treatment Guidelines for COVID-19

Prepared: November 2020. Contact: Kelly Echevarria, PharmD, BCPS, AQ-ID, BCIDP, National Clinical Pharmacy Program Manager, VA Pharmacy Benefits Management Services 10P4P

Updated version may be found at [PBM INTERNet](#) or [PBM INTRANet](#)

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6. When I had a patient denied Remdesivir by the Infectious Diseases service quoting the November VA directive, I contacted Richard Stone, M.D., VHA Chief Medical Executive (the Trump Administration's title for the Under Secretary for Health, VHA, DVA). Dr. Stone contacted VA Pharmacy Management Services and the Medical Advisory Board. At first, the VA responded

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**Treatment:** Passive Immunization: COVID-19 Convalescent Plasma and Antibodies and Antivirals

**Prevention:** Active Immunization: Vaccines

to me. But when the VA became evasive, I contacted the FDA, the NIAID (Case #12276), and wrote a letter to the editors of the *The New England Journal of Medicine*. None responded to me.

7. I recently had a patient admitted to the Surgical Service who had newly turned COVID-19 positive (less than 24 hours from negative to positive). The recommendations from the same Infectious Diseases service was that if the patient had any symptomatology like headache or neck pain, give three days of Remdesivir; and if the patient develops a cough, give five days of Remdesivir and dexamethasone. By the time of that consult, the CDC had stated a month before that Regeneron's and Eli Lilly's monoclonal cocktails were ineffective against COVID-19, omicron variant; and, thus, GlaxoSmithKline's *sotrovimab* was and is being *de facto* rationed at present time.

Once again, I thank all involved in addressing my question at Gilead regarding if a phase I study had been completed in the case of Remdesivir. You were all very professional and willing to listen—and, most of all, my personal thanks as a Federal Physician and Surgeon for you have provided this information which may become an outstanding service for the people of the United States of America.

Thank you,  
Charles Andrus, M.D., F.A.C.S.  
Professor, Department of Surgery, Saint Louis University School of Medicine

Chief and Attending General Surgeon, Unit II (SLU) General Surgery division, Surgical Service,  
John Cochran (112JC), St. Louis, MO 63106

Office phone: 314-652-4100 ext 54463 Beeper: 314-491-2417  
Home phone: 314-455-9482

P.S. I hope this e-mail will initiate an overall discussion regarding transparency by the agencies of the U.S. Government in regards to the EARLY (< 72 hours from diagnosis) administration with intent of synergism of COVID-19 Convalescent Plasma, COVID-19 monoclonal antibodies, Remdesivir and other future antivirals, etc. Respectfully, Charles H. Andrus, M.D., F.A.C.S.

**From:** Public Affairs <Public\_affairs@gilead.com>  
**Sent:** Wednesday, February 16, 2022 7:54 AM  
**To:** Andrus, Charles H. (STL) <Charles.Andrus@va.gov>  
**Subject:** [EXTERNAL] Phase 1 remdesivir trial results

Dr. Andrus,

You can find the published results of the Phase 1 remdesivir trial here:  
<https://ascpt.onlinelibrary.wiley.com/doi/10.1111/cts.12840> (reference #466 of this chronological bibliography)

Thank you for your inquiry,

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**Prevention:** Active Immunization: Vaccines

Gilead Public Affairs

- 1132) 2022-02-22 Adler B: Trump praises Putin's 'genius' incursion into Ukraine.  
<https://news.yahoo.com/trump-praises-putins-genius-incursion-into-ukraine-234001858.html>
- 1133) 2022-02-25 CDC: COVID-19—People with certain medical conditions.  
<https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html>
- 1134) 2022-02-27 Campbell C: 'Almost treasonous': Romney condemns GOP backing Putin.  
<https://www.aol.com/news/almost-treasonous-romney-condemns-gop-171557057.html>
- 1135) 2020-02-27 Moore M: US hints at war-crimes tribunal after Ukraine accuses Russia of genocide. New York Post. <https://nypost.com/2022/02/27/us-hints-at-war-crimes-tribunal-after-ukraine-accuses-russia-of-genocide/>
- 1136) 2022-02-27 Reuters: World Court: Ukraine has filed suit against Russia, citing false genocide claims. <https://www.reuters.com/world/europe/icc-says-may-investigate-possible-war-crimes-after-russian-invasion-ukraine-2022-02-25/>
- 1137) 2022-02-27 Bancroft H, Gregory A, Rai A: Ukraine-Russian news live: Putin puts nuclear forces on high alert as Zelensky calls for foreign fighters. Independent.  
<https://www.independent.co.uk/news/world/europe/russia-ukraine-crisis-latest-putin-kyiv-zelensky-war-update-b2024247.html>
- 1138) 2022-02-28 iSpot.tv: Pfizer, Inc. TV Spot, 'Move Fast: Oral Treatment'.  
<https://www.ispot.tv/ad/bAea/pfizer-inc-move-fast-oral-treatment>

**DEAR MR. PRESIDENT:**

**WHAT FOLLOWS IS THE FDA DISCLAIMER REGARDING THE ADVERTIZEMENT IN WHICH THE "ORAL MEDICATION in the treatment of COVID-19" IS AUTHORIZED UNDER AN EUA BUT NOT APPROVED BY THE FDA FOR THE USE TO TREAT EARLY (<120 HOURS FROM ONSET) COVID 19.**

Mr. President: You may ask, Why the legal semantics? Well, it is probably a violation of Federal Law that Pfizer is advertising Paxlovid (the advertisement never calls the antiviral by name—as Merck also has an experimental oral antiviral authorized by the FDA under an

EUA and both are under EUAs); *while* Remdesivir (VEKLURY) **HAS BEEN AN FDA approved and authorized PRESCRIPTION intravenous antiviral DRUG**

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**designated FOR use in THE EARLY TREATMENT OF COVID-19 SINCE October 22, 2020. In short, your administration has bought 20 million boxes (30 pills per box (1 five day treatment dose) for a total of 600 million—0.6 billion pills—of an experimental antiviral, PAXLOVID, in the “TEST to TREAT initiative”—which is outstanding. These experimental oral antivirals under EUAs are in direct commercial competition with an FDA approved, authorized intravenous prescription drug: VEKLURY (Remdesivir) which could have been administered in EVERY INFUSION CENTER, OUTPATIENT SURGICENTER, AND HOSPITAL IN THE U.S.A. FOR THE LAST 20 MONTHS—but was withheld by general medical ignorance, the pharmaceutical industry’s arrogance and greed, and federal incompetence and conflicts-of-interests.**

Charles H. Andrus, M.D., F.A.C.S., May 15, 2022

[https://www.covid19oralrx-patient.com/?source=google&HBX\\_PK=s\\_paxlovid&skwid=43700068270576697&gclid=EAIaIQobChMIIsliA49fY9gIVk5JbCh0sxA4PEAAAYASAAEgLZs\\_D\\_BwE&gclsrc=aw.ds](https://www.covid19oralrx-patient.com/?source=google&HBX_PK=s_paxlovid&skwid=43700068270576697&gclid=EAIaIQobChMIIsliA49fY9gIVk5JbCh0sxA4PEAAAYASAAEgLZs_D_BwE&gclsrc=aw.ds)

## **Authorized Use**

**The FDA has authorized the emergency use of PAXLOVID, an investigational medicine, for the treatment of mild-to-moderate COVID-19 in adults and children (12 years of age and older weighing at least 88 pounds [40 kg]) with a positive test for the virus that causes COVID-19, and who are at high risk for progression to severe COVID-19, including hospitalization or death, under an EUA.**

**PAXLOVID is investigational because it is still being studied. There is limited information about the safety and effectiveness of using PAXLOVID to treat people with mild-to-moderate COVID-19.**

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**Prevention:** *Active Immunization:* Vaccines

## Pfizer

PAXLOVID™ (nirmatrelvir tablets; ritonavir tablets)

Now Authorized for Emergency Use

**PAXLOVID has not been approved, but has been authorized for emergency use by FDA under an EUA, for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death.**

- 1139)** 2022-03-01 Biden J: Remarks of President Joe Biden – State of the Union Address as Prepared for Delivery. *The White House, Briefing Room, March 1, 2022, Speeches and Remarks.* <https://www.whitehouse.gov/briefing-room/speeches-remarks/2022/03/01/remarks-of-president-joe-biden-state-of-the-union-address-as-delivered/>

...I remember when my Dad had to leave our home in Scranton, Pennsylvania to find work. I grew up in a family where if the price of food went up, you felt it.

That's why one of the first things I did as President was fight to pass the American Rescue Plan.

Because people were hurting. We needed to act, and we did.

Few pieces of legislation have done more in a critical moment in our history to lift us out of crisis.

It fueled our efforts to vaccinate the nation and combat COVID-19. It delivered immediate economic relief for tens of millions of Americans.

Helped put food on their table, keep a roof over their heads, and cut the cost of health insurance.

And as my Dad used to say, it gave people a little breathing room.

And unlike the \$2 Trillion tax cut passed in the previous administration that benefitted the top 1% of Americans, the American Rescue Plan helped working people—and left no one behind. ...

... For more than two years, COVID-19 has impacted every decision in our lives and the life of the nation.

And I know you're tired, frustrated, and exhausted.

But I also know this.

Because of the progress we've made, because of your resilience and the tools we have, tonight I can say

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we are moving forward safely, back to more normal routines.

We've reached a new moment in the fight against COVID-19, with severe cases down to a level not seen since last July.

Just a few days ago, the Centers for Disease Control and Prevention—the CDC—issued new mask guidelines.

Under these new guidelines, most Americans in most of the country can now be mask free.

And based on the projections, more of the country will reach that point across the next couple of weeks.

Thanks to the progress we have made this past year, COVID-19 need no longer control our lives.

I know some are talking about “living with COVID-19”. Tonight – I say that we will never just accept living with COVID-19.

We will continue to combat the virus as we do other diseases. And because this is a virus that mutates and spreads, we will stay on guard.

Here are four common sense steps as we move forward safely.

First, stay protected with vaccines and treatments. We know how incredibly effective vaccines are. If you're vaccinated and boosted you have the highest degree of protection.

We will never give up on vaccinating more Americans. Now, I know parents with kids under 5 are eager to see a vaccine authorized for their children.

The scientists are working hard to get that done and we'll be ready with plenty of vaccines when they do.

We're also ready with anti-viral treatments. If you get COVID-19, the Pfizer pill reduces your chances of ending up in the hospital by 90%.

We've ordered more of these pills than anyone in the world. And Pfizer is working overtime to get us 1 Million pills this month and more than double that next month.

And we're launching the “Test to Treat” initiative so people can get tested at a pharmacy, and if they're positive, receive antiviral pills on the spot at no cost.

If you're immunocompromised or have some other vulnerability, we have treatments and free high-quality masks.

We're leaving no one behind or ignoring anyone's needs as we move forward.

And on testing, we have made hundreds of millions of tests available for you to order for free.

Even if you already ordered free tests tonight, I am announcing that you can order more from covidtests.gov starting next week.

Second – we must prepare for new variants. Over the past year, we've gotten much better at detecting new variants.

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If necessary, we'll be able to deploy new vaccines within 100 days instead of many more months or years.

And, if Congress provides the funds we need, we'll have new stockpiles of tests, masks, and pills ready if needed.

I cannot promise a new variant won't come. But I can promise you we'll do everything within our power to be ready if it does.

Third – we can end the shutdown of schools and businesses. We have the tools we need.

It's time for Americans to get back to work and fill our great downtowns again. People working from home can feel safe to begin to return to the office.

We're doing that here in the federal government. The vast majority of federal workers will once again work in person.

Our schools are open. Let's keep it that way. Our kids need to be in school.

And with 75% of adult Americans fully vaccinated and hospitalizations down by 77%, most Americans can remove their masks, return to work, stay in the classroom, and move forward safely.

We achieved this because we provided free vaccines, treatments, tests, and masks.

Of course, continuing this costs money.

I will soon send Congress a request.

The vast majority of Americans have used these tools and may want to again, so I expect Congress to pass it quickly.

Fourth, we will continue vaccinating the world.

We've sent 475 Million vaccine doses to 112 countries, more than any other nation.

And we won't stop.

We have lost so much to COVID-19. Time with one another. And worst of all, so much loss of life.

Let's use this moment to reset. Let's stop looking at COVID-19 as a partisan dividing line and see it for what it is: A God-awful disease.

Let's stop seeing each other as enemies, and start seeing each other for who we really are: Fellow Americans.

We can't change how divided we've been. But we can change how we move forward—on COVID-19 and other issues we must face together. ...

...And fourth, let's end cancer as we know it.

This is personal to me and Jill, to Kamala, and to so many of you.

Cancer is the #2 cause of death in America—second only to heart disease.

Last month, I announced our plan to supercharge  
the Cancer Moonshot that President Obama asked me to lead six years ago.

Our goal is to cut the cancer death rate by at least 50% over the next 25 years, turn more cancers  
from death sentences into treatable diseases.

More support for patients and families.

To get there, I call on Congress to fund ARPA-H, the Advanced Research Projects Agency for  
Health.

It's based on DARPA—the Defense Department project that led to the Internet, GPS, and so much  
more.

ARPA-H will have a singular purpose—to drive breakthroughs in  
cancer, Alzheimer's, diabetes, and more.

- 1140)** 2022-03-01 Satyanarayana M: Nasal spray COVID preventives are finally in  
development – Different methods of drug delivery give us more tools to fight disease.  
Scientific American. [https://www.scientificamerican.com/article/nasal-spray-covid-  
preventives-are-finally-in-development1/](https://www.scientificamerican.com/article/nasal-spray-covid-preventives-are-finally-in-development1/)

- 1141)** 2022-03-06 Brewster A, Gomez Fin: Trump renews NATO criticism after Russia's  
invasion of Ukraine, and also say "vote counter" can be more important than candidate. CBS  
News <https://www.cbsnews.com/news/trump-russia-ukraine-nato-elections/>

Trump's remarks came about 24 hours after former Vice President Mike Pence took several shots  
at Trump during his address to the same donor retreat, which is taking place in New Orleans.

Pence told them Friday evening that "there is no room in this party for apologists for Putin" —  
days after Trump had referred to the Russian president as "smart" and "savvy." On Saturday  
evening, Trump mentioned that "somebody called me a Putin apologist the other day," but didn't  
bring up Pence, according to a source.

- 1142)** 2022-03-07 Casadevall A, Grossman BJ, Joyner MJ, Henderson JP, Paneth N, Pirofski  
LA, Shoham S: National COVID-19 Convalescent Plasma Project. Last digitized for  
International Archive, March 7, 2022. <https://ccpp19.org/about/index.html>

- 1143)** 2022-03-08 HHS.gov: Fact Sheet: Biden administration launches nationwide Test-to-  
Treat initiative ensuring rapid 'On the Spot' access to lifesaving COVID treatments.  
<https://www.hhs.gov/about/news/2022/03/08/fact-sheet-biden-administration-launches->

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[nationwide-test-treat-initiative-ensuring-rapid-on-spot-access-lifesaving-covid-treatments.html](#)

- 1144) 2022-03-09 Rubin R: Once viewed as a promising COVID-19 treatment, convalescent plasma falls out of favor. JAMA network  
<https://jamanetwork.com/journals/jama/fullarticle/2790074?guestAccess>

In the pandemic's initial dark days, physicians and patients and their families were desperate for effective COVID-19 treatments. They didn't yet have monoclonal antibodies or antiviral pills to lessen the ravages of the disease, so many turned to a therapy more than a century old.

At the very least, they figured, **convalescent plasma**, donated by people who'd recovered from COVID-19, couldn't hurt, and the SARS-CoV-2 antibodies it was presumed to contain could enhance patients' defenses against COVID-19.

"There was a preconceived notion of efficacy," H. Clifford Lane, MD, deputy director for clinical research and special projects at the National Institute of Allergy and Infectious Diseases, said in a recent interview.

Three reports from Wuhan, China, published in 2020 in *JAMA*, the *Proceedings of the National Academy of Sciences*, and the *Journal of Medical Virology*, showed that patients' viral load decreased and their symptoms improved following infusions of convalescent plasma. But the studies involved only a total of 21 patients; the authors of all 3 articles noted that clinical trials were needed to confirm the findings.

Nevertheless, while trials were being planned, US hospitals began infusing patients with COVID-19 with convalescent plasma through the US Food and Drug Administration's (FDA's) Expanded Access Program (EAP). **Approximately 94 000** people hospitalized with COVID-19 in the US had received convalescent plasma infusions by August 2020, when the FDA **ended** the EAP and authorized the golden liquid for emergency use.

A December 2021 analysis of **EAP data** in *PLOS Medicine* demonstrated convalescent plasma's safety in patients hospitalized with COVID-19—the incidence of serious adverse events was less than 1%. But because the study didn't include a control or comparator group, "the data should not be used to infer definitive treatment effects," the authors noted.

As other COVID-19 treatments became available, convalescent plasma's early promise didn't pan out in randomized clinical trials. "I don't think convalescent plasma is a first-line therapy at this point," Kevin Schulman, MD, a professor of medicine at the Stanford University School of Medicine who has studied the treatment, said in an interview.

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## Panic Instead of Science?

Convalescent plasma wasn't associated with clinical benefit in a recent *JAMA Network Open* meta-analysis that pooled findings from 8 randomized clinical trials involving 2341 hospitalized patients breathing without the aid of mechanical ventilation, 1231 of whom received the treatment.

A UK trial published too recently to be considered for inclusion in the meta-analysis reached a similar conclusion. It randomized 11 558 hospitalized patients—5% of whom were receiving invasive mechanical ventilation upon randomization—to receive usual care plus convalescent plasma or only usual care. Researchers found that convalescent plasma did not improve survival or progression to ventilation.

In addition, a recently published multicenter placebo-controlled trial randomized 511 high-risk outpatients with COVID-19 who came to emergency departments within 7 days of symptom onset. The study found that convalescent plasma didn't prevent disease progression.

"We've moved on," said Schulman, a coauthor of the emergency department trial. "Convalescent plasma is a great thing to think about very early in a pandemic."

Instead of providing an untested treatment to tens of thousands of patients in the EAP, multiple, large clinical trials could have been conducted, Schulman said. But, he added, a "huge amount of desperation" early in the pandemic "turned into panic, not into science."

Large clinical trials, with 2500 patients apiece, could have answered questions that still remain, such as identifying the optimal dose and timing of convalescent plasma treatment and which patients are likely to benefit, Schulman said.

"You could easily argue we underdosed patients" in his trial, Schulman acknowledged. "Our trial was the best we could do at the time."

## All in the Timing?

Arturo Casadevall, MD, PhD, a leader of the National COVID-19 Convalescent Plasma Project, isn't ready to abandon a treatment he's championed since penning a *Wall Street Journal* op-ed about it in February 2020.

"In the spring of 2020, I really thought that convalescent plasma was a safety raft to new therapies that would be available in the fall," Casadevall, chair of molecular microbiology and immunology at the Johns Hopkins Bloomberg School of Public Health, said in a recent interview.



Casadevall said he would have liked to conduct clinical trials with some of the patients enrolled in the EAP, but funding wasn't available. Instead, he took a different approach to try to assess convalescent plasma's efficacy: He tracked the number of convalescent plasma units that blood banking organizations dispensed to hospitals per admission and COVID-19 deaths in the fall of 2020. Casadevall and his collaborators **found** a strong inverse correlation between convalescent plasma use per COVID-19 hospital admission and deaths from the disease occurring 2 weeks after admission.

The problem with the randomized trials is that they didn't treat patients soon enough to make a difference, Casadevall said.

Only trials in which patients receive convalescent plasma early in their infection could be expected to show a treatment benefit, he explained. By the time patients require hospitalization for COVID-19, the horse is already out of the barn. At that point, Casadevall said, inflammation is the problem, so anti-SARS-CoV-2 antibodies wouldn't help slow disease progression. (Similarly, **no anti-SARS-CoV-2 monoclonal antibody product has been authorized** for patients with severe COVID-19.) The National COVID-19 Convalescent Plasma Project has posted critiques of Schulman's study, the UK trial, and other research on its **website**.

Casadevall coauthored a recent multicenter **trial** that randomized 1225 outpatients whose COVID-19 symptoms had begun within 8 days before enrollment. The study, which hasn't been peer-reviewed, found that early administration of high-titer SARS-CoV-2 convalescent plasma reduced hospitalizations over the next 28 days by 54% compared with control plasma from donors who had not had COVID-19.

"High titer convalescent plasma is an effective early outpatient COVID-19 treatment with advantages of low cost, wide availability, and rapid resilience to variant emergence from viral genetic drift in the face of a changing pandemic," Casadevall and his coauthors concluded.

## Limiting Its Use

Despite Casadevall's favorable finding, recently updated guidelines from the World Health Organization (WHO), the FDA, and the Infectious Diseases Society of America (IDSA) recommend only limited use of convalescent plasma, if that.

On February 8, 2022, IDSA strongly **recommended against** using convalescent plasma in patients hospitalized with COVID-19. Among ambulatory patients with mild to moderate disease who are at high risk of progression to more serious symptoms and have no other treatment options, infusing high-titer COVID-19 convalescent plasma within 8 days of symptom onset is better than not infusing it, according to the guideline, which described this as a conditional recommendation with low certainty of evidence.

The FDA's **most recent revision** of the Emergency Use Authorization (EUA) for COVID-19 convalescent plasma, published December 28, 2021, limits treatment with high-titer COVID-19 convalescent plasma to patients who have immunosuppressive disease or are receiving immunosuppressive treatment.

Randomized clinical trials and observational studies show that convalescent plasma is unlikely to be associated with clinical benefit in immunocompetent individuals with COVID-19, according to the FDA.

Interestingly, the WHO **recommends against its use** for patients who *aren't* severely ill, calling the evidence for that position "certain." Convalescent plasma should be used only within clinical trials for severe and critical patients with COVID-19, the WHO said in December 2021.

In a **letter** to the *BMJ*, Casadevall and coauthors urged the WHO to reconsider, saying that the organization "avoided digging below the surface to ask critical questions about treatment timing, study populations, and antibody titre" of the convalescent plasma in the trials it considered.

For now, demand for convalescent plasma is low because the clinical trial findings in hospitalized patients have persuaded many physicians that it won't benefit any patients, Casadevall said. On top of that, he said, "Medicine has gotten used to working with therapies that are very well-defined. Plasma is a therapy where physicians are uncomfortable because every unit is different. To many people, that just doesn't feel right."

Lane is among those people. "It's not a uniform product," he noted. Assays suggested by the FDA measure only antibodies to the spike protein of 1 variant, so it's difficult to know the true level and nature of antibodies in a unit of convalescent plasma, Lane said.

And it's virtually impossible to judge a unit of plasma by its donor, Lane said. "Typically, the sicker you are, the better your antibodies." Younger people also tend to generate more antibodies than older people, he added. However, "the immune response to SARS-CoV-2 is highly variable."

Other COVID-19 treatments are standardized, so physicians can know exactly what they're giving patients, Lane said. "If you have an at-risk ambulatory patient with symptoms, you can give them Paxlovid [nirmatrelvir and ritonavir, Pfizer's antiviral pill], you can give them remdesivir. You can reduce their risk of being hospitalized 80% to 85%, and you know what you've given."

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## Article Information

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**Published Online:** March 9, 2022. doi:[10.1001/jama.2022.3214](https://doi.org/10.1001/jama.2022.3214)

**Conflict of Interest Disclosures:** Dr Schulman reports receiving personal fees from Novartis and from Frazier Healthcare Partners. Dr Casadevall reports that he is involved in convalescent plasma clinical trials at Johns Hopkins and serves on the scientific board of SAB Biotherapeutics, an antibody company.

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## II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited as follows:

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- Distribution of the authorized PAXLOVID will be controlled by the United States (U.S.) Government for use consistent with the terms and conditions of this EUA. Pfizer will supply PAXLOVID to authorized distributor(s)<sup>4</sup>, who will distribute to healthcare facilities or healthcare providers as directed by the U.S. Government, in collaboration with state and local government authorities as needed;
- PAXLOVID may only be used by healthcare providers to treat mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk<sup>5</sup> for progression to severe COVID-19, including hospitalization or death;

#### Limitations on Authorized Use

- PAXLOVID is not authorized for initiation of treatment in patients requiring hospitalization due to severe or critical COVID-19.<sup>6</sup>
- PAXLOVID is not authorized for use as pre-exposure or as post-exposure prophylaxis for prevention of COVID-19.
- PAXLOVID is not authorized for use for longer than 5 consecutive days.
- PAXLOVID may only be prescribed for an individual patient by physicians, advanced practice registered nurses, and physician assistants that are licensed or authorized under state law to prescribe drugs in the therapeutic class to which PAXLOVID belongs (i.e., anti-infectives).<sup>7</sup>
- The use of PAXLOVID covered by this authorization must be in accordance with the authorized Fact Sheets.

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